

EXHIBIT 36

1 UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 IN RE: NATIONAL)
5 PRESCRIPTION) MDL No. 2804
6 OPIATE LITIGATION)
7 _____) Case No.
8) 1:17-MD-2804
9)
10 THIS DOCUMENT RELATES) Hon. Dan A.
11 TO ALL CASES) Polster
12)

13 FRIDAY, NOVEMBER 16, 2018

14 HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
15 CONFIDENTIALITY REVIEW

16 - - -

17 Videotaped deposition of James
18 Rausch, held at the offices of STINSON
19 LEONARD STREET LLP, 7700 Forsyth Boulevard,
20 Suite 1000, St. Louis, Missouri, commencing
21 at 9:00 a.m., on the above date, before
22 Carrie A. Campbell, Registered Diplomat
23 Reporter and Certified Realtime Reporter.

24 - - -

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INDEX	PAGE
APPEARANCES.....	2
EXAMINATIONS	
BY MR. KAWAMOTO.....	10
BY MS. HERZFELD.....	301
BY MR. TSAI.....	336
BY MR. KAWAMOTO.....	340
EXHIBITS	
No. Description Page	
11 Mallinckrodt E-mail(s), 76	
12 Rausch 1 MNK-T1_0000273559 -	
13 MNK-T1_0000273562	
14 Mallinckrodt September 27, 2006 letter 76	
15 Rausch 2 from the US Department of	
16 Justice, Drug Enforcement	
17 Administration to	
18 registrants,	
19 MNK-T1_0000273563 -	
20 MNK-T1_0000273566	
21 Mallinckrodt E-mail(s), 93	
22 Rausch 3 MNK-T1_0000419874 -	
23 MNK-T1_0000419875	
24 Mallinckrodt December 27, 2007 letter 93	
25 Rausch 4 from the US Department of	
Justice, Drug Enforcement	
Administration to	
registrants,	
MNK-T1_0000421084 -	
MNK-T1_0000421085	

Page 6	Page 8
<p>1 Mallinckrodt Mallinckrodt Controlled 126 Rausch 5 Substance Suspicious Order Monitoring Program, Introductory Training for Field Sales, June 5, 2008 2 Mallinckrodt DEA Compliance Procedure, 151 Rausch 6 Draft 3, published 6/2/08, MNK-T1_0000419993 - MNK-T1_0000419997 3 4 Mallinckrodt Suspicious Order Monitoring 196 Rausch 7 Program, Dosage Products Shipment from Hobart, Activities 08/2008 through 08/2010, MNK-T1_0000477900 - MNK-T1_0000477912 5 6 Mallinckrodt Peculiar Order Process, 231 Rausch 8 MNK-T1_0000264431 - MNK-T1_0000264432 7 8 Mallinckrodt November 2, 2010 Memorandum 236 Rausch 9 from Howard Davis to Karen Harper, MNK-T1_0000269399 - MNK-T1_0000269400 9 10 Mallinckrodt Standard Operating 244 Rausch 10 Procedure, Due diligence procedures and monitoring of controlled substances sales, MNK-T1_0000269401 - MNK-T1_0000269406 11 12 Mallinckrodt E-mail(s), 275 Rausch 11 MNK-T1_0000307119 13 Mallinckrodt E-mail(s), 279 Rausch 12 MNK-T1_0000266788 14 15 Mallinckrodt E-mail(s), 282 Rausch 13 MNK-T1_0000266994 - MNK-T1_0000266997 16 17 18 19 20 21 22 23 24 25</p>	<p>1 VIDEOGRAPHER: We're now on the 2 record. My name is James Arndt. I'm 3 a videographer for Golkow Litigation 4 Services. 5 Today's date is November 16, 6 2018, and the time is 9 a.m. 7 This video deposition is being 8 held in St. Louis, Missouri, in the 9 matter of the National Prescription 10 Opiate Litigation for the United 11 States District Court, Northern 12 District of Ohio, Eastern Division. 13 The deponent is Jim Rausch. 14 Will counsel please identify 15 themselves for the record? 16 MR. KAWAMOTO: Dean Kawamoto, 17 Gary Gotto and Erika Keech from Keller 18 Rohrbach on behalf of the MDL 19 plaintiffs. 20 MR. TSAI: Good morning. Rocky 21 Tsai, Ropes & Gray, representing the 22 witness and Mallinckrodt. 23 MR. DAVISON: William Davison, 24 Ropes & Gray, representing the witness 25 and Mallinckrodt.</p>
Page 7	Page 9
<p>1 Mallinckrodt E-mail(s), 286 Rausch 14 MNK-T1_0000266735 - 2 MNK-T1_0000266736 3 Mallinckrodt E-mail(s), 291 Rausch 15 MNK-T1_0000266730 4 5 Mallinckrodt E-mail(s), 293 Rausch 16 MNK-T1_0000298447 6 Mallinckrodt E-mail(s), 298 Rausch 17 MNK-T1_0000387257 - 7 MNK-T1_0000387258 8 (Exhibits attached to the deposition.) 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>	<p>1 MR. TILLY: Jason Tilly, 2 Mallinckrodt Pharmaceuticals. 3 MS. CONWAY: Sarah Conway on 4 behalf of Walmart. 5 MS. HERZFELD: Tricia Herzfeld 6 on behalf of plaintiffs for the 7 Tennessee state litigation. 8 VIDEOGRAPHER: The court 9 reporter is Carrie Campbell, and she 10 will now swear in the witness. 11 MR. YINGLING: Yeah, this is 12 Patrick Yingling for 13 AmerisourceBergen. 14 MR. PERSKIE: Jacob Perskie 15 from Fox Rothschild for Validus 16 Pharmaceuticals in the Arkansas 17 matter. 18 MS. YOCUM: Michelle Yocum from 19 on behalf of McKesson. 20 MS. MCNAMARA: Colleen McNamara 21 on behalf of Cardinal Health. 22 MR. RICARD: Paul Ricard on 23 behalf of Prescription Supply, Inc. 24 25</p>

Page 10

1 JAMES RAUSCH,
2 of lawful age, having been first duly sworn
3 to tell the truth, the whole truth and
4 nothing but the truth, deposes and says on
5 behalf of the Plaintiffs, as follows:
6
7 DIRECT EXAMINATION
8 QUESTIONS BY MR. KAWAMOTO:
9 Q. Good morning, Mr. Rausch.
10 A. Good morning.
11 Q. Thank you for being here today.
12 So my name is Dean, and my
13 colleagues are Gary and Erika.
14 I'm going to plan to take a
15 break probably around every hour, but if you
16 need one earlier, just please let me know.
17 A. Okay.
18 Q. Could you please state your
19 name and business address?
20 A. James Rausch, and I'm currently
21 retired.
22 Q. And you understand that you're
23 under oath, right, sir?
24 A. Yes.
25 Q. And are you taking any

Page 11

1 medications, or is there any other reason
2 that would interfere with your ability to
3 answer my questions fully and truthfully?
4 A. I'm taking medications, but it
5 wouldn't interfere with being able to answer
6 the questions.
7 Q. Thank you.
8 And if I ask a question you
9 don't understand, please let me know and I
10 will try to rephrase it.
11 A. Okay.
12 Q. Have you ever testified in a
13 deposition?
14 A. No.
15 Q. Okay. So some basic ground
16 rules, just primarily for the benefit of the
17 court reporter, but it's very important that
18 when I ask you a question, that you answer
19 verbally as opposed to nodding or shaking
20 your head.
21 A. Okay.
22 Q. And it's also very important
23 that we not speak over each other. So I'll
24 ask my question, and then I'll let you
25 answer.

Page 12

1 Your attorney may object for
2 the record. Unless he instructs you not to
3 answer, though, you are to answer the
4 question.
5 A. Okay.
6 Q. Have you ever testified at
7 trial?
8 A. One -- once.
9 Q. And can you describe the --
10 well, what was the nature of that trial?
11 A. Someone stole firearms from my
12 house -- or my apartment at the time. I went
13 to testify on identifying the firearm.
14 Q. And who are the other people
15 seated next to you today?
16 A. These are the lawyers
17 representing Mallinckrodt.
18 Q. And are they also your
19 attorneys?
20 A. They represent me.
21 Q. Okay. And are you paying them
22 to be here today?
23 A. No.
24 Q. Okay. Do you know who is
25 paying them?

Page 13

1 A. Mallinckrodt.
2 Q. So, sir, I want to ask you a
3 few questions about your deposition
4 preparation.
5 Did you review any documents in
6 preparation for this deposition?
7 A. That's attorney-client
8 privilege.
9 Q. My understanding, and Rocky can
10 object if he feels he needs to, but I'm not
11 asking you to identify for me the documents
12 that you reviewed. I just want to know if
13 you reviewed any documents.
14 MR. TSAI: You can answer that
15 question.
16 THE WITNESS: Yes.
17 QUESTIONS BY MR. KAWAMOTO:
18 Q. Okay. And did you review any
19 deposition transcripts or other trial
20 testimony?
21 A. No.
22 Q. And did you review any expert
23 reports?
24 A. Excerpt reports?
25 Q. Expert reports.

Page 14

1 A. No.
2 Q. My apologies.
3 Do you recall reviewing any
4 court documents?
5 A. No.
6 Q. And what about any electronic
7 records, for example, any databases?
8 A. No.
9 Q. Now, have you looked at your
10 own personal paper or electronic files to
11 prepare for this deposition?
12 A. No, I've been retired for
13 almost six years.
14 Q. Now, I take it you spoke with
15 your attorneys prior to this deposition; is
16 that fair?
17 A. Yes.
18 Q. And do you recall whether it
19 was in person or by phone or both?
20 A. In person.
21 Q. And on how many occasions did
22 you speak with them?
23 A. Three times.
24 Q. And do you recall roughly how
25 many hours on each occasion it was?

Page 15

1 A. Four or five hours, roughly.
2 Q. And this is four or five hours
3 each time?
4 A. Yes.
5 Q. Okay. And at these meetings,
6 who was present?
7 A. Rocky and Bill.
8 Q. And so no one else was present
9 other than --
10 A. No.
11 Q. -- Rocky and Bill?
12 Now, you indicated that you
13 reviewed documents.
14 Did any of those documents
15 refresh your recollection regarding the
16 issues at this deposition?
17 A. Yes. Considering that I've
18 been retired for six years, so I had not seen
19 any of these documents for quite a long time.
20 MR. KAWAMOTO: Okay. And I
21 take it, Mr. Tsai, if I ask him to
22 identify those documents, you'll
23 object on privilege?
24 MR. TSAI: Yes.
25 MR. KAWAMOTO: Okay. So I will

Page 16

1 ask you to identify those -- I will
2 ask you to identify those documents.
3 Rocky?
4 MR. TSAI: I object on
5 attorney-client privilege and work
6 product grounds, and I instruct the
7 witness not to answer to the extent
8 the question is asking him to identify
9 documents that were selected and
10 compiled by counsel and discussed with
11 counsel.
12 QUESTIONS BY MR. KAWAMOTO:
13 Q. Okay. So I'm going to try to
14 modify that question, and your attorney may
15 also have the same objection.
16 But can you generally describe
17 for me the categories of documents that you
18 looked at to refresh your recollection?
19 A. I believe that's
20 attorney-client privilege.
21 E-mails, I guess, would be the
22 answer to that.
23 Q. And other than your attorneys,
24 did you speak to anyone else to prepare for
25 your deposition?

Page 17

1 A. No, sir.
2 Q. Okay. Now, sir, are you being
3 reimbursed by anyone for your expenses in
4 connection with this deposition?
5 A. No, sir.
6 Q. And so Mallinckrodt is not
7 compensating you for your time in connection
8 with this deposition?
9 A. No, sir.
10 Q. Can you brief -- strike that.
11 Can you briefly describe your
12 education background after high school?
13 A. I went to college for three
14 years in pursuit of a major in psychology,
15 and -- I was hired -- this was in '76, I was
16 hired as -- at Mallinckrodt as a summer
17 replacement for people going on vacation, and
18 I ended up staying on full time, so I never
19 did finish school.
20 Q. And roughly when you did you
21 start working at Mallinckrodt?
22 A. 1976.
23 Q. And you say you retired six
24 years ago. So forgive my math, but that
25 would be 2012?

Page 18

1 A. 2013. January.
 2 Q. Okay. And so between 1976 and
 3 2013, you were employed by Mallinckrodt?
 4 A. That's correct.
 5 Q. And so you've never worked for
 6 anyone else other than Mallinckrodt?
 7 A. Correct.
 8 Q. Have you completed any
 9 nondegree programs of study?
 10 And if you don't understand
 11 what that means, I'm happy to clarify.
 12 A. Would you clarify that?
 13 Q. Have you taken any other
 14 courses or any training outside of
 15 Mallinckrodt, for example, any -- do you have
 16 any regulatory certifications or professional
 17 licenses?
 18 A. No.
 19 Q. So I would like to ask you
 20 about your employment at Mallinckrodt, and
 21 recognizing that it covers 1976 to 2013, it's
 22 a broad time period, so I'll understand if
 23 you don't remember the details, particularly
 24 from the earlier time.
 25 But can you generally walk me

Page 19

1 through the different positions that you've
 2 held since starting at Mallinckrodt?
 3 A. Sure, I'll try.
 4 As I said, in 1976 I was hired
 5 as a replacement for -- in customer service.
 6 It was a business that no longer is with
 7 Mallinckrodt.
 8 And I eventually was hired full
 9 time, and after about a year, that business
 10 moved to Paris, Kentucky, and I stayed in
 11 St. Louis and got a position in the
 12 production and inventory control area in our
 13 bulk business.
 14 Q. Okay. And if I could pause you
 15 there.
 16 So when were you hired full
 17 time, roughly what year?
 18 A. It was in '76.
 19 Q. And you were initially hired
 20 into customer service for a business that
 21 subsequently moved?
 22 A. Right.
 23 Q. A business line that
 24 subsequently moved?
 25 A. Right.

Page 20

1 Q. And then when did you go to
 2 production and inventory, roughly what year?
 3 A. I would say '77.
 4 Q. Okay. And I'm sorry, go ahead.
 5 You were saying something about, I think it
 6 was a bulk business?
 7 A. Yes, the bulk business that
 8 Mallinckrodt had there. I was a production
 9 and inventory control planner.
 10 Q. And what did that entail? I'm
 11 not familiar with that term.
 12 A. It entailed planning the
 13 production of inventory for material that was
 14 to be sold. Based upon inventory levels, we
 15 would -- we would plan the raw materials that
 16 needed to be brought in and then the
 17 production schedules for the production of
 18 the material.
 19 Q. And so you're talking about raw
 20 materials that would be, I guess, turned into
 21 pharmaceuticals?
 22 A. This is not pharmaceuticals at
 23 that time. I was not in the
 24 pharmaceutical -- I was in the specialty
 25 chemical business, which was for raw

Page 21

1 materials that went into food -- food --
 2 foods and industrial applications. This was
 3 all down in our St. Louis plant. And this
 4 was a raw material; it was not a finished
 5 good.
 6 Q. And so is it fair to say that
 7 your job was to make sure that you had
 8 sufficient amounts of the raw materials to
 9 make the needed amounts of the finished
 10 goods?
 11 A. That was part of it, yes, to
 12 make sure that the raw materials were
 13 scheduled to be brought in on time so when we
 14 were scheduling the run for making the
 15 product that we wanted to make was there in
 16 time.
 17 Q. Okay. And how long did you
 18 continue with those responsibilities?
 19 A. I did that from
 20 approximately -- well, I was a planner for
 21 several years, and then I became a supervisor
 22 over four or five planners, and I was in that
 23 position until '91, and then I went to work
 24 in customer service as a manager.
 25 Q. And was that still related to

<p style="text-align: right;">Page 22</p> <p>1 raw chemicals in -- or was that in 2 pharmaceuticals? 3 A. Yes, still -- I had the 4 acetaminophen, our acetaminophen customer 5 service group, I had our specialty chemical 6 group, and our bulk narcotic group reporting 7 to me. 8 Q. Okay. 9 A. And I reported into the sales 10 for the -- for the bulk area. 11 Q. And what is -- what is the 12 specialty chemical group? 13 A. Well, like I said, the 14 specialty chemical group is for raw materials 15 for us to produce finished good, raw 16 materials for, say, food applications. We 17 sold raw materials to Anheuser Busch. We 18 sold industrial chemicals, but they were all 19 raw material and then they would further take 20 our raw material and combine it with their 21 raw materials to make finished good or 22 whatever application they were using it for. 23 Q. And none of these raw materials 24 related to the manufacture of opioids; is 25 that fair?</p>	<p style="text-align: right;">Page 24</p> <p>1 continued to be a raw material. That was 2 considered our finished good. 3 Q. Okay. 4 A. And was sold in bulk 5 quantities, hundred -- hundred kilos or 6 hundred pounds at a time. 7 Q. So I just want to make sure 8 that I've got the timing correct. 9 So in '91 you became a manager 10 and -- you became a manager of the 11 acetaminophen customer service group, the 12 specialty chemical group and the bulk 13 narcotic group; is that correct? 14 A. That's correct. 15 Q. And did you -- did you later go 16 on other positions, or did you stay in that 17 position? 18 A. Yes, I had that position until 19 approximately the fall of 2008, and then I 20 took over customer service for the dosage 21 business. 22 Q. And can you describe for me 23 what the dosage business is? 24 A. The dosage business is when you 25 take raw material products, opiate products,</p>
<p style="text-align: right;">Page 23</p> <p>1 A. That was another group. That 2 was our -- that was our bulk narcotic group. 3 Q. Okay. And what -- can you 4 define for me, what is a bulk -- or what is a 5 bulk narcotic group? 6 A. A bulk narcotic is a -- a raw 7 material that we produce from opiate and the 8 raw material is then sold to another 9 manufacturer who adds chemical -- other 10 chemicals to that -- our raw material to make 11 a finished product. Pills, powder, tablets. 12 We did not make a finished 13 good, product, in the bulk area. 14 Q. And the pills and powders and 15 tablets, that would later be sold to, for 16 example, distributors? 17 A. Yes, from the manufacturers 18 that we sold to. 19 Q. And when you say that you did 20 not make a finished good or a product, that's 21 with respect to the bulk narcotics; is that 22 correct? 23 A. Correct. And when I say 24 "finished good," in your terms, it was not in 25 a tablet form or whatever. It was a --</p>	<p style="text-align: right;">Page 25</p> <p>1 and combine them with other chemicals to make 2 a finished good in the tablet or powder form. 3 Q. So when you say you take raw 4 material products, this was Mallinckrodt raw 5 material products and making them into opioid 6 products? 7 A. Yes. 8 Q. And these opioid products would 9 subsequently be shipped out to Mallinckrodt's 10 customers; is that correct? 11 A. Yes. Our distributor customers 12 and that, yes. 13 Q. And you held this position from 14 2008 until you retired in 2012 -- or I'm 15 sorry, 2013? 16 A. Correct. 17 Q. Who was your predecessor in 18 this position -- I'm sorry, in this position? 19 A. Cathy Stewart. 20 Q. I know if I -- if I could go 21 back to the -- the bulk narcotics business 22 for a second. 23 A. Yes. 24 Q. Do you recall who the 25 manufacturers were who purchased bulk</p>

Page 26

1 narcotics from Mallinckrodt?

2 A. Oh, gosh. Purdue was one of

3 the bigger ones. I don't remember -- I don't

4 remember all of them.

5 Q. Well, do you recall if Endo

6 purchased any?

7 A. Endo, I believe, was one of

8 them, yes.

9 Q. Okay. What about Teva?

10 A. Yes.

11 Q. What about Allergan?

12 A. I believe so.

13 Q. Okay. How about Johnson &

14 Johnson?

15 A. Yes.

16 Q. How about Janssen?

17 A. I believe so.

18 Q. So in the context of the bulk

19 narcotics business, you sold to most of the

20 major manufacturers in the market; is that

21 fair?

22 A. Yes.

23 Q. Sir, was your retirement

24 voluntary?

25 A. Yes.

Page 27

1 Q. So you could have stayed on if

2 you wanted to; you just decided it was time

3 to go?

4 A. Yes.

5 Q. And can you briefly -- well,

6 strike that.

7 The position you held from fall

8 of 2008 until 2013, what was your title?

9 A. Manager of customer service.

10 Q. And it was manager of customer

11 service for dosage products, is that the

12 full --

13 A. Yes.

14 Q. And what was your compen --

15 well, what was your compensation scheme for

16 your -- for your position?

17 In other words, were you paid a

18 base? Did you also have a bonus? How was

19 that determined?

20 A. At the time I reported into the

21 logistics group, which included customer

22 service, shipping and warehousing, and we did

23 have a bonus that was based upon backorders,

24 how long it took us to -- to answer the

25 phone, that type of thing. Very

Page 28

1 customer-service-based compensation.

2 Q. So do you recall in -- for

3 2012, what was your base compensation?

4 A. As far as dollars?

5 Q. Yes.

6 A. I don't remember.

7 Q. And do you recall what your

8 bonus was?

9 A. Oh, my base as far as salary?

10 Q. Yes, your base salary.

11 A. It was probably around 90,000.

12 Q. And then do you recall what

13 your bonus was for that year?

14 A. No. But it was like 10 percent

15 was the -- was the most I could make, if I

16 met my objectives.

17 MR. TSAI: And, Dean, I know

18 that the depo transcripts are

19 presumptively highly confidential, but

20 because you're getting into personal

21 financial information, I do want to

22 designate this discussion as highly

23 confidential.

24 MR. KAWAMOTO: Sure, that's

25 fine.

Page 29

1 QUESTIONS BY MR. KAWAMOTO:

2 Q. And the \$90,000, was this --

3 was this more or less your base salary for

4 the 2008 to 2013 time period?

5 A. Well, we had yearly reviews,

6 and based upon reviews and if you met your

7 goals and that type of thing, depending on

8 what the percentage was for that year, you

9 know, it could go up or stay the same.

10 Q. And were your reviews generally

11 positive in your opinion?

12 A. Yes. Yes.

13 Q. Did anyone ever express any

14 concerns about your performance?

15 A. No.

16 Q. And in terms of your goals,

17 what are the goals that you recall that you

18 were evaluated based on?

19 A. I don't remember many of them.

20 It's been a long time. But again, like I

21 said, it was based upon, say, call answering

22 rate, we needed to have it above 95 percent,

23 so we would keep track of that, and that

24 would be one goal.

25 Keeping our backorders down to,

Page 30

1 I forget what percentage, was another goal.
2 We had other goals as far as
3 having the CSRs attend -- or sign up for
4 different seminars, and we were responsible
5 for making sure that they met their goals
6 there. So that was another thing that we
7 were graded on.
8 Just a few that I can think of.
9 Q. Were any of these goals
10 compliance related?
11 A. Karen Harper would have yearly,
12 if I remember right, a review of what was
13 going on in compliance and kind of keep us
14 abreast of any -- any new regulations or
15 anything like that that we may need to know
16 about.
17 Q. And so was your compensation
18 based, in part, on your ability to comply
19 with these regulations?
20 A. No.
21 Q. And who reported to you?
22 You were a manager, so who were
23 the people under you?
24 A. I had five CSRs and one being a
25 lead.

Page 31

1 Q. Okay. And do you recall their
2 names?
3 A. No, not all of them. Brenda
4 Raycop was the lead. I don't remember the
5 rest of their names.
6 Q. And who did you report to?
7 A. Well, at one time it was
8 Michael Pheney and George -- last one was
9 George -- I forget his last name now.
10 Q. Is it George Saffold?
11 A. Saffold, yes.
12 Q. And you mentioned Karen Harper.
13 A. Yes.
14 Q. Did you report to her?
15 A. No.
16 Q. So going back to the bulk
17 narcotics business.
18 Who would you say were your
19 main competitors in that field?
20 A. Back then, we didn't have a
21 whole lot of competitors within the United
22 States. We had a -- we had a sizeable
23 percentage of the -- of the production that
24 the DEA allowed within the country. I don't
25 remember who they were, but it wasn't --

Page 32

1 there wasn't many because the DEA wanted to
2 keep control of where the production -- how
3 much production was being put out and who was
4 producing it.
5 Q. So would you describe yourself
6 as one -- as essentially the dominant player
7 in the bulk narcotics business?
8 A. I would say we were --
9 MR. TSAI: Object to the form.
10 Go ahead.
11 THE WITNESS: -- we were one of
12 the larger producers.
13 QUESTIONS BY MR. KAWAMOTO:
14 Q. And who were the other larger
15 producers in that space?
16 A. Like I said, I don't remember.
17 Q. Would you -- do you believe you
18 were the largest producer in that space?
19 MR. TSAI: Objection. Vague as
20 to time.
21 THE WITNESS: Yes, it depends
22 on the time frame that we're speaking.
23 Early on we were probably one
24 of the largest ones. I'm not saying
25 we were the largest or not, I don't

Page 33

1 remember, but we were in the top
2 three, I would say.
3 QUESTIONS BY MR. KAWAMOTO:
4 Q. So, no, I understand that there
5 are limits to your memory.
6 A. Right.
7 Q. So what was the time frame
8 where you would -- where it would be fair to
9 say you were probably one of the largest?
10 A. Well, like I said, I don't
11 remember.
12 Q. Roughly would this be in the
13 2000s? In the '90s?
14 A. Roughly, probably in the '90s
15 and early 2000.
16 Q. And then I guess when you say
17 early 2000s, are we talking like 2005 to
18 2000 -- I'm sorry, 2000 to 2005 or 2006?
19 A. 2000 to 2005 would be -- from
20 what I remember.
21 Q. And then after 2005, you were
22 still a large producer; you just weren't the
23 largest; is that fair?
24 A. That's true.
25 Q. Now, focusing on your position

Page 34

1 from 2008 to 2013, which is when you were the
2 customer service manager for dosage products.
3 A. Okay.
4 Q. What training did you receive
5 for your -- for that position?
6 A. Training was mostly done by the
7 previous customer service rep or manager,
8 Cathy Stewart.
9 Q. And do you recall what she did
10 to train you?
11 A. We just went over the processes
12 that the CSRs and that had to -- what was
13 needed as far as orders, forms needed from
14 the customers before we could ship orders
15 out, who their customers were, the product
16 line, that type of thing.
17 Q. And when you say "who their
18 customers were," were you -- are you
19 referring to Mallinckrodt's direct customers
20 or the customers of your customer?
21 A. Mallinckrodt's direct
22 customers.
23 Q. And when you say "product
24 line," what are you referring to?
25 A. This -- the products that we

Page 35

1 sold in the finished good form. We're
2 talking about hydrocodone, oxycodone,
3 codeine, those type of products.
4 Q. And are you referring to
5 Mallinckrodt's generic products?
6 A. Yes.
7 Q. Okay. Would the product lines
8 you're responsible for also include
9 Mallinckrodt's branded products?
10 A. Yes.
11 Q. Now, are you familiar with the
12 term "suspicious order monitoring"?
13 A. Yes, I am.
14 Q. What does that term mean to
15 you?
16 A. It was a process -- well,
17 depends on what time frame we're talking
18 about. When I was in the bulk business as a
19 customer service manager, when we first
20 developed the suspicious order monitoring
21 program requested by our St. Louis DEA, it
22 was a monthly report that we sent to them
23 showing orders that were out of the ordinary
24 as far as quantity or frequency, that type of
25 a report. It was sent to our DEA field

Page 36

1 office on a monthly basis.
2 Q. I'm sorry.
3 And roughly what time frame was
4 this process in effect for?
5 A. Probably 2000 -- and I'm
6 guessing because I don't remember exactly
7 when we started, when they requested this.
8 But I would say probably 2003,
9 '4 to 2006 or '7.
10 Q. And I take it the process then
11 changed in 2006 or '7?
12 A. That's -- that's correct.
13 Q. Okay. And what was that
14 different process then?
15 A. We started working on a more
16 enhanced suspicious order program at the
17 request of our compliance group to automate
18 it so we were capturing information on orders
19 at the time of -- the order was entered. It
20 was based upon a lot more detail than what we
21 had previously been supplying the DEA. The
22 DEA was in the process of changing what they
23 wanted to see and what they wanted to see
24 their customers, I'll call them, or the
25 registrants, what they wanted from them, from

Page 37

1 the registrants, and it became more complex
2 than what we had previously.
3 Q. And so I guess for simplicity's
4 sake, I will refer to the earlier suspicious
5 order monitoring program as the pre-2007
6 program, and then the enhanced one is either
7 the enhanced SOM or the post-2007; does that
8 make sense?
9 A. That's fine.
10 Q. Okay. So for the pre-2007 SOM
11 program, how did you identify the suspicious
12 orders?
13 A. It was -- the system -- it was
14 put into our order entry system and it was
15 based upon a log rhythm {sic} that we had
16 come up with and designed and was approved by
17 the DEA field office based upon the average
18 order quantity. And I believe it was 2 X was
19 the quantity that would flag an order on our
20 system -- 2 X meaning two times the normal
21 order pattern that the customer placed. And
22 it was a -- a running total. So it wasn't
23 just based upon a year. It was based upon
24 the previous 12 rolling months.
25 Q. And so just so I understand

Page 38

1 sort of mathematically how this works, are
 2 you essentially looking at the average over
 3 the past 12 months and then seeing if the new
 4 order is more than two times that average?
 5 A. That's correct.
 6 Q. Okay. So if the average -- I
 7 understand that there may be different sort
 8 of metrics, but if the average I had was,
 9 let's say, 50 bottles per month --
 10 A. Correct.
 11 Q. -- that means that my new order
 12 could be, I guess, up to a hundred bottles;
 13 is that fair?
 14 A. Correct.
 15 Q. Okay.
 16 A. And keep in mind we not only
 17 had the suspicious order monitoring program,
 18 but the customers that we sold to also had to
 19 supply quota forms and that, which was issued
 20 by the DEA, on what they could buy. And 222
 21 forms was another requirement giving -- that
 22 had to be supplied with every order that they
 23 placed.
 24 Q. And are they -- when you say
 25 "quota forms," is that the same as the 222

Page 39

1 form?
 2 A. Quota forms were forms that
 3 were used for raw material manufacturers.
 4 222 forms were used for
 5 researchers and other type of registrants and
 6 also for the dosage customers who were
 7 ordering Schedule II products.
 8 Q. Okay. So you wouldn't need
 9 both a quota form or a 22 form --
 10 A. Right.
 11 Q. -- or a 222 form.
 12 It was one or the other?
 13 A. Depending on their
 14 registration.
 15 Q. And for the 222 form, what
 16 would that tell you?
 17 A. Are we getting away from the
 18 bulk side?
 19 Q. Yes, why don't we focus on
 20 dosage and then we can come back to bulk.
 21 A. Okay.
 22 Q. Because the 222 form isn't used
 23 in connection with bulk, correct?
 24 A. No, the 222 form had to match
 25 the order that they were placing.

Page 40

1 Q. And when you say it "had to
 2 match," what does that mean?
 3 A. It couldn't be more than -- the
 4 order couldn't be more than what was on the
 5 222 form.
 6 Q. Okay.
 7 A. And the 222 form was -- was
 8 received from the DEA.
 9 Q. And so the DEA would tell
 10 the -- would tell the --
 11 A. Yes.
 12 Q. -- your customer how much they
 13 could order on a monthly basis?
 14 A. I don't think it was on a
 15 monthly basis. It was based -- I'm not sure.
 16 I don't remember how the customer would get
 17 their 222 form, but everybody in the quota
 18 system -- the DEA would take -- the DEA would
 19 take the total amount of a particular
 20 product, like let's just say one product that
 21 was sold in a particular year, and they would
 22 look at that and that's the base of what we
 23 are going to allow to be sold the following
 24 year.
 25 Some customers, like

Page 41

1 Mallinckrodt, would get a portion of that,
 2 other manufacturers would get a portion of
 3 that, and it was based upon their previous
 4 sales. Okay. The same would be for the
 5 distributors.
 6 And that's what they would
 7 start off with for the year, how much they
 8 could buy, and the way that they bought it
 9 was with a 222 form, which the DEA would give
 10 them these forms in advance and they had --
 11 they would, I guess, request more as they
 12 needed them.
 13 Q. Okay.
 14 A. Just as long as it was within
 15 their quota limits.
 16 Q. So it sounds like there are
 17 essentially two quotas being imposed:
 18 There's one being imposed on Mallinckrodt,
 19 and then there's another one --
 20 A. As a manufacturer.
 21 Q. Yes, one being imposed on
 22 Mallinckrodt as a manufacturer. Thank you.
 23 A. Right.
 24 Q. And one being imposed on
 25 Mallinckrodt's customers, which it sounds

Page 42

1 like are distributors?
 2 A. If you're looking at the bulk
 3 side, again, we're a bulk manufacturer and
 4 we're selling to bulk manufacturers who add,
 5 so they would buy it on their procurement
 6 quota, okay, so they would send us a quota
 7 form, too.
 8 Q. Okay. So is the only
 9 difference between a quota form and a 222
 10 form the nature of the customer submitting
 11 the form?
 12 A. It's the nature of their
 13 registration.
 14 Q. Okay. And so focusing on the
 15 dosage products, let's say I'm a distributor
 16 and the DEA has given me a quota of
 17 50 million pills, let's say, for the year.
 18 A. Okay.
 19 Q. And Mallinckrodt has a quota
 20 of, you know, 200 million pills.
 21 A. Okay.
 22 Q. I take it this means that my
 23 222 form that I submit to Mallinckrodt can't
 24 exceed 50 million; is that right?
 25 A. How much did you say they had?

Page 43

1 Q. Well, my overall quota is
 2 50 million.
 3 A. Right.
 4 Q. For the entire year, though.
 5 A. Right.
 6 Q. So when I submit a 222 form to
 7 Mallinckrodt, I mean, I assume so long as the
 8 number is not higher than 50 million, then
 9 it's okay?
 10 I'm trying to sort of
 11 understand what the -- what the limit is for
 12 the specific 222 form in any given month.
 13 A. Well, keep in mind that they
 14 wouldn't be bringing in 50 million tablets
 15 into their inventory. They didn't want to
 16 keep that kind of inventory. And that,
 17 again, would call fall under the suspicious
 18 order monitoring program, so that large of a
 19 quantity at one time would be brought to the
 20 attention of the DEA, and the DEA would look
 21 into why they're ordering so much at one
 22 time.
 23 Q. Understood.
 24 But as a general matter, the
 25 222 form -- well, the quota being applied to

Page 44

1 the 222 form was likely going to
 2 significantly exceed any monthly order that
 3 the customer placed; is that fair?
 4 A. Correct.
 5 Q. Okay. So it's not as if the
 6 222 form is really directly limiting the
 7 monthly order of a customer.
 8 The check on how much that
 9 customer can order on a monthly basis would
 10 be Mallinckrodt's algorithm?
 11 A. Yes.
 12 Q. And that algorithm for the
 13 2000 -- the pre-2007 time period was based on
 14 two times your yearly average -- I'm sorry,
 15 your yearly monthly average?
 16 A. Are we speaking on bulk?
 17 Q. No, I was talking about dosage
 18 products.
 19 A. Oh, okay.
 20 I'm not -- I didn't have it at
 21 that time. I believe they did have a similar
 22 report, but I'm not sure what the algorithm
 23 was at the time. That came under Cathy
 24 Stewart's watch.
 25 Q. But for the bulk products that

Page 45

1 you were in charge of --
 2 A. Uh-huh.
 3 Q. -- the algorithm was two times
 4 the monthly average?
 5 A. From what I remember, that's
 6 true.
 7 Q. Okay.
 8 A. Rolling average.
 9 Q. And I'm sorry, what's the
 10 difference between a rolling average and --
 11 A. It's not a calendar -- it's not
 12 a calendar period. It's a 12-month period.
 13 Q. Okay. So it's still 12 months.
 14 It's just you don't go from January to
 15 January.
 16 A. Correct.
 17 Q. Okay. And so in the bulk
 18 context, if my monthly average was, let's
 19 say, 50 kilograms --
 20 A. Okay.
 21 Q. -- I could go up to a hundred
 22 kilograms on my next order?
 23 A. Correct.
 24 Q. And then, of course, if I order
 25 a hundred kilograms, that would affect my

Page 46

1 average.
 2 A. Correct.
 3 Q. And so, you know, over -- over
 4 time, if you're using a two times algorithm,
 5 you know, the monthly limit on what you can
 6 order could increase significantly; isn't
 7 that fair?
 8 MR. TSAI: Object to the form.
 9 THE WITNESS: It could.
 10 QUESTIONS BY MR. KAWAMOTO:
 11 Q. And was there any -- well, if
 12 you were to look at --
 13 A. But keep in mind --
 14 Q. Sorry, go ahead.
 15 A. But keep in mind, you know,
 16 they could increase their -- what they were
 17 ordering as long as it was within their quota
 18 from the DEA.
 19 Q. Understood.
 20 A. And then outside of our monthly
 21 report that went to the DEA, which the DEA
 22 was fine with, okay, with what we used for
 23 our criteria, we also -- the customer service
 24 reps were quite familiar with who our
 25 customers were and -- because there wasn't a

Page 47

1 huge number of bulk manufacturers that we
 2 were dealing with, like there wasn't new
 3 players all the time, so we had a pretty good
 4 understanding of what their needs were.
 5 So if there was something out
 6 of the ordinary that our CSRs saw, they would
 7 bring it to the attention of Karen Harper and
 8 just make her aware of it if she felt there
 9 was a need to look into it with the DEA or
 10 whatever.
 11 Q. And this is for the bulk
 12 narcotics process, correct?
 13 A. That's correct. That's what
 14 we're speaking to, yes.
 15 Q. And so in 2008, who took your
 16 place in -- with respect to bulk narcotics?
 17 Who assumed your position?
 18 A. Cathy Stewart. So we switched.
 19 Q. Okay. You switched.
 20 And do you recall who has or do
 21 you know who has your position now with
 22 respect to dosage products?
 23 A. No, I sure don't.
 24 Q. Okay. So, sir, you're aware
 25 that this case is about opioids; is that

Page 48

1 fair?
 2 A. That's true, yes.
 3 Q. Would you believe that there is
 4 an opioid -- that there's an opioid crisis in
 5 this country?
 6 A. That's what I have heard, yes.
 7 Q. And when you say that that's
 8 what you've heard, what do you mean by that?
 9 A. Well, on the news and that,
 10 I've heard that there's been an opioid
 11 epidemic, yes.
 12 Q. And you believe that's
 13 accurate?
 14 A. I can only, you know -- from
 15 what I've heard. I don't know personally.
 16 Q. But you don't have any reason
 17 to believe that that's -- that that's not
 18 true?
 19 A. No.
 20 Q. Do you believe that the drugs
 21 sold by Mallinckrodt contributed to this
 22 epidemic?
 23 A. That's a -- that's a -- no, I
 24 don't believe that, and why I say that is
 25 Mallinckrodt was -- was at the top of the --

Page 49

1 what I'll call the chain in that we
 2 manufactured the product. We did not
 3 manufacture the -- we manufactured it, we
 4 shipped it, sold it to our distributors, the
 5 distributors sold it to the pharmacies, the
 6 pharmacies sold it to the physicians and the
 7 physicians sold it to -- or prescribed it to
 8 the patients. We were not in the position
 9 to, I guess, ever send the pills to an end
 10 user.
 11 Q. Well, when you say that there
 12 is an opioid epidemic, what's your
 13 understanding of the nature of the epidemic?
 14 A. I didn't say -- I agree with
 15 you that I believe that from what I've heard
 16 that there is.
 17 Q. Okay. So you've heard that --
 18 you've heard there's an opioid epidemic?
 19 A. Uh-huh.
 20 Q. What is your understanding of
 21 the nature of that epidemic?
 22 A. Well, it's from diversion of
 23 not only prescription medicine but from
 24 illegal products that are coming from other
 25 countries, that type of thing. It's not --

Page 50

1 it's not all prescribed or prescription,
2 controlled medication.
3 Q. Would you agree that the
4 prescription controlled medication is a
5 significant component of this epidemic?
6 A. I -- from what I've read or
7 heard.
8 Q. And when you say "diversion,"
9 what do you mean by that?
10 A. It's not being prescribed for
11 its intended use.
12 Q. And when you say "prescribed
13 for its intended use," what does that mean?
14 A. For medical purposes. For the
15 control -- what I consider medical use is
16 that the pills -- or the product that we sold
17 to other manufacturers who made a finished
18 good, intended use was for pain relief, okay,
19 and for people that were suffering from
20 long-term illness that needed pain relief,
21 cancer patients, surgery, people that had
22 surgery, that's what the intended use of the
23 opiates that we sold were for.
24 Q. And I'm just reading along --
25 I'm just reading on the screen, but you

Page 51

1 indicated that your understanding is that the
2 products being sold by Mallinckrodt were for
3 long-term illness that needed pain relief,
4 cancer patients and surgery, essentially
5 cancer pain or acute pain; is that fair?
6 A. Some of that, yeah. Some of
7 the major applications.
8 Q. Okay. Do you understand what
9 chronic pain is?
10 MR. TSAI: Objection to the
11 form.
12 Go ahead.
13 THE WITNESS: Chronic pain is
14 from -- what my understanding of it is
15 is for people that are constantly in
16 pain. Okay. I can say like my
17 brother-in-law who has a chronic pain
18 in his back, and it's just every day
19 is a hard time getting out of bed.
20 QUESTIONS BY MR. KAWAMOTO:
21 Q. And so in your opinion should
22 he be on opioids?
23 MR. TSAI: Object to the form.
24 Go ahead.
25 THE WITNESS: In my opinion?

Page 52

1 QUESTIONS BY MR. KAWAMOTO:
2 Q. Yes.
3 A. That's up to his doctor.
4 Q. Do you believe that opioids are
5 addictive?
6 A. I believe that they can be
7 addictive if they're abused.
8 Q. And do you believe that opioids
9 are being abused?
10 A. From my understanding and what
11 I've heard, yes, they can be abused.
12 Q. Okay. And what are the risk
13 factors for opioid abuse? Do you know what
14 any of them are?
15 A. I'm not familiar with it.
16 Q. Now, I just wanted to make sure
17 I understood your -- your understanding of
18 what the term "diversion" is.
19 But what -- could you define
20 "diversion" for me?
21 A. The way I think of diversion is
22 that the -- something that is being used
23 for -- is not being used for its intended use
24 I guess is the simplest way I can think of
25 it.

Page 53

1 Q. And when you say "not being
2 used for its intended use," what do you mean
3 by that?
4 Are you talking about the
5 doctor is not appropriately prescribing it,
6 or what -- what do you mean by "not being
7 used for intended use"?
8 A. I guess that that would be part
9 of it, yes, that the doctor is prescribing
10 maybe more than what the patient needs or
11 product is being brought over from other
12 countries, that type of thing. It's not for
13 its intended use as a medical need, I guess.
14 Q. So the fact that a patient is
15 taking an opioid pursuant to a prescription
16 doesn't necessarily mean that the patient is
17 not abusing opioids; is that fair?
18 A. Saying that again?
19 Q. The fact that a patient is
20 taking opioids pursuant to a prescription
21 from a doctor --
22 A. Pursuant to a prescription.
23 Q. -- does not mean that the
24 patient -- well, strike that. Let me reask
25 that question.

Page 54

1 A doctor could misprescribe
2 opioids; is that fair?
3 A. I guess they could.
4 Q. And you've indicated that would
5 be one example of diversion?
6 A. Yes.
7 Q. Okay. So if you had a patient
8 that was taking opioids pursuant to a
9 prescription that was improper, that patient
10 would be abusing opioids, notwithstanding the
11 fact they had a prescription?
12 MR. TSAI: Object to the form.
13 THE WITNESS: I guess -- I
14 guess that's possible.
15 QUESTIONS BY MR. KAWAMOTO:
16 Q. And so in terms of what the
17 problems are with diversion or what the harms
18 are with diversion, what in your opinion are
19 the problems or harms stemming from
20 diversion, the diversion of opioids?
21 MR. TSAI: Object to the form.
22 THE WITNESS: In my opinion as
23 a layman?
24 QUESTIONS BY MR. KAWAMOTO:
25 Q. Well, in your opinion as

Page 55

1 someone that's worked for Mallinckrodt from
2 1976 to 2013 and spent the past -- well, the
3 past 12-plus years in their business.
4 A. Well, I would say if they
5 weren't using it for its intended use as a
6 medicinal pain reliever, then I guess it
7 could be abused. And if they abused it, they
8 could be -- become medically dependent on it.
9 Q. And so diversion, one of the
10 consequences of diversion, could be abuse and
11 addiction; is that fair?
12 A. Correct.
13 Q. Did you ever have any concerns
14 about diversion while you were working for
15 Mallinckrodt?
16 A. It was always a concern that we
17 have the proper tools in place to keep that
18 from happening, and I felt that we did with
19 the regulations that we filed -- that were
20 given to us by the DEA as far as needing the
21 222 forms, in the bulk side, the quota forms.
22 Also we had the necessary data collection
23 that the DEA asked us to submit to them,
24 which went from the monthly letters to a more
25 sophisticated reporting system. Later on as

Page 56

1 the DEA changed their needs, our requirements
2 for us, I felt we had the controls in place
3 to meet that.
4 Q. Did others at Mallinckrodt ever
5 express any concerns to you regarding
6 diversion of Mallinckrodt products, opioid
7 products?
8 A. That there was a diversion
9 problem?
10 Q. That there either was a
11 diversion problem or that there was a risk of
12 Mallinckrodt products being diverted?
13 A. No.
14 MR. TSAI: Objection.
15 Compound.
16 Go ahead.
17 THE WITNESS: No, not that I
18 remember. Everybody -- everybody was
19 doing what they could in making sure
20 that we were meeting the needs of
21 the -- meeting the DEA compliance
22 needs.
23 QUESTIONS BY MR. KAWAMOTO:
24 Q. And did you understand
25 diversion to be an issue of corporate concern

Page 57

1 for Mallinckrodt?
2 A. I believe it was a corporate
3 concern, and that's one of the reasons why
4 our controls were so -- so tight.
5 Q. And when you say your "controls
6 were so tight," what controls are you talking
7 about? Could you list them for me?
8 A. Well, what I mean by that is
9 what we've discussed already is that we were
10 meeting the compliance of the DEA regulations
11 with requiring the quota letters and the 222
12 forms, which were required, also the letter
13 that we -- and bulk, also on dosage, that we
14 were asked to submit on a monthly basis early
15 on. And then as the regulations -- or as the
16 DEA tightened their regulations and asked us
17 to submit more than just the letters and
18 actually end the letters and to come up with
19 a more robust -- more robust suspicious order
20 monitoring program, we did that going
21 forward.
22 I always felt that Mallinckrodt
23 was a -- felt that it was very important as a
24 citizen -- I'm calling Mallinckrodt as a
25 citizen -- to adhere and meet the needs of

Page 58

1 what the DEA was requiring over and beyond
2 anything. That was kind of our corporate
3 goal, I guess I would say.
4 MR. TSAI: Dean, we've been
5 going about an hour.
6 MR. KAWAMOTO: Sure, why don't
7 we take -- why don't we take a
8 ten-minute break.
9 VIDEOGRAPHER: We're going off
10 the record at 10 a.m.
11 (Off the record at 10:00 a.m.)
12 VIDEOGRAPHER: We're back on
13 the record at 10:21 a.m.
14 QUESTIONS BY MR. KAWAMOTO:
15 Q. So, Mr. Rausch, you indicated
16 that in 2008 you and Cathy Stewart
17 essentially switched jobs.
18 A. Yes.
19 Q. So you went to dosage products,
20 and she went to bulk narcotics.
21 A. That's correct.
22 Q. Why did you switch?
23 A. Our boss at the time, George
24 Saffold, wanted us to switch to learn more
25 about the other areas.

Page 59

1 Q. And "the other areas" meaning
2 he wanted you to learn more about dosage
3 products and her to learn more about bulk
4 narcotics?
5 A. That's correct, right.
6 Q. Did George have any concerns
7 about Cathy's stewardship of the dosage
8 products?
9 A. No.
10 MR. TSAI: Object to the form.
11 QUESTIONS BY MR. KAWAMOTO:
12 Q. Okay. And would you view your
13 switch in 2008 as a promotion for you?
14 A. No, it was a lateral.
15 Q. Now, do you recall our prior
16 discussion regarding the quota system?
17 A. Yes.
18 Q. Okay. And so I want to focus
19 now on bulk narcotics with respect to the
20 quota system.
21 Well, I guess why are quotas
22 important?
23 A. Quotas are important -- and
24 again, I'm speaking as a customer service
25 person. I'm not, you know, privy to all the

Page 60

1 regulations that, like, Karen Harper in the
2 compliance group would be.
3 But from what I remember, the
4 quota system was important in -- for the DEA
5 to keep track of what was being used in the
6 United States. So like I had mentioned
7 earlier, the DEA would take all the quota,
8 all the -- all the quota letters and forms
9 and the 222 forms that were used -- and I'm
10 not only talking, you know, from the
11 distributors but also from the pharmacists
12 and everyone else that had to report to the
13 DEA what they were using during the year --
14 they would take that, add it all up and see
15 what the total was for United States for a
16 particular product. And they would use that
17 for their base for what they were going to
18 allow the following year. So that's why the
19 reporting through the quota system was very,
20 very important.
21 Q. And you had indicated that the
22 compliance with the quota system was an
23 element of Mallinckrodt's efforts to fight
24 diversion; is that fair?
25 A. Well, I wouldn't say it was

Page 61

1 that. You know, it was to meet the
2 regulations that were given to us by the DEA.
3 As a good citizen, Mallinckrodt
4 being a good citizen, we felt it was very
5 important that we follow the regulations in
6 that to keep something like diversion from
7 happening.
8 Q. And so what are -- what are all
9 of the steps -- focusing now on the bulk
10 narcotics side, what are all of the steps
11 that Mallinckrodt took to ensure that the
12 quota system was being complied with?
13 A. We would -- we would require
14 from our customers, along with their order,
15 to send us a quota form under their license,
16 whether they're a manufacturer or a
17 researcher or whatever license they had, they
18 had to send us a quota form, and we would not
19 use -- we could not ship that order until
20 that form was sent to us. And what we would
21 do with the quota form is then turn that into
22 our compliance group.
23 Q. And did the -- did the quota
24 form indicate their overall quota for the
25 year?

Page 62

1 A. No, usually it was the amount
 2 that they were ordering. It couldn't be more
 3 than what was on the order.
 4 Q. And so how -- how would
 5 Mallinckrodt know that this order -- that the
 6 order -- that the newest order your customer
 7 had submitted didn't exceed their quota for
 8 the year?
 9 A. It would show the total, I
 10 believe, if I'm -- and I'm trying to
 11 remember. I think it would show the total,
 12 but then it would also show what they're
 13 using for that particular order.
 14 Q. And when you say "total," I'm
 15 sorry, what total are you referring to?
 16 A. You're asking what -- how we
 17 knew what the customer's total was?
 18 Q. My apologies. So let me
 19 rephrase that question.
 20 The quota form which showed the
 21 total amount of that narcotic they had
 22 received that year?
 23 A. That they were ordering from
 24 us.
 25 Q. Okay. Understood. But I guess

Page 63

1 my question may be a little different.
 2 So let's say the DEA gives
 3 Manufacturer A a quota of a hundred
 4 kilograms?
 5 A. Uh-huh.
 6 Q. And Mallinckrodt -- and they
 7 submit an order to Mallinckrodt asking to
 8 purchase 3 kilograms.
 9 A. Okay.
 10 Q. How does Mallinckrodt know
 11 that -- whether that 3-kilogram order is
 12 going to exceed their hundred-kilogram quota?
 13 A. It would show the total and
 14 then what had been used so far, from what I
 15 remember.
 16 Q. So your recollection is that
 17 the quota form is going to show their overall
 18 quota, so a hundred kilograms?
 19 A. Right.
 20 Q. Plus the amount that they had
 21 ordered up -- so the total amount they had
 22 ordered thus far for the year?
 23 A. I believe so, from what I
 24 remember.
 25 Q. And was that just orders for

Page 64

1 Mallinckrodt, or was that all orders?
 2 A. It would be all orders.
 3 Q. Okay. So if Manufacturer A
 4 were ordering, you know, bulk product from
 5 Mallinckrodt and three other manufacturers,
 6 the quota form is going to show the total
 7 amount they had received from all of those
 8 other manufacturers?
 9 A. Yes.
 10 Q. And did Mallinckrodt take any
 11 steps to ensure that those numbers were
 12 accurate?
 13 A. Customer service wasn't
 14 responsible for that, so we would turn in the
 15 forms to our -- to compliance groups, so that
 16 would be for them to determine that. They
 17 reported through their system, which was the
 18 ARCOS system, which I'm not that familiar
 19 with, but that's how they reported what the
 20 manufacturer or our customers had taken from
 21 us or sold to them from us.
 22 Q. And ARCOS would tell you how
 23 much -- ARCOS would give you the amount of
 24 product that the manufacturer had obtained
 25 from Mallinckrodt.

Page 65

1 Would it also provide you with
 2 the information as to how much they had
 3 obtained from everyone else?
 4 A. I would to refer you to Karen
 5 Harper on that.
 6 Q. And going over to the dosage
 7 side, what was the system in place on the
 8 dosage side to ensure that the quota system
 9 was being complied with?
 10 A. The customer had to give us a
 11 222 form that matched the order quantity that
 12 they were ordering, and that 222 form would
 13 then sent -- be sent to our compliance
 14 person, and they would gather all that --
 15 those compliance forms, I believe, on a
 16 monthly basis and send them to the DEA.
 17 But, again, that's the
 18 compliance group, and I would refer you to
 19 them for more information.
 20 Q. And did the 222 form also
 21 contain the total quota assigned to that
 22 distributor?
 23 A. No, I don't believe it did,
 24 from what I remember. It was just for that
 25 particular order.

Page 66

1 Q. So I guess going back to my
2 question from the bulk side.
3 A. Uh-huh.
4 Q. With respect to the dosage side
5 of the business, how did Mallinckrodt know
6 that -- well, strike that.
7 So let's take the following
8 hypothetical: Distributor A has a quota from
9 DEA for a hundred pills.
10 A. Uh-huh.
11 Q. It submits a 222 form to
12 Mallinckrodt asking to buy ten pills.
13 How does Mallinckrodt know that
14 those ten pills don't exceed the hundred-pill
15 quota?
16 A. We probably wouldn't, but
17 remember that the DEA is issuing the 222
18 form, so they -- as we turn in -- or we and
19 whoever else they're buying from -- the 222
20 forms back to the DEA, the DEA would give
21 them new 222 forms based upon what was left.
22 Q. And do you know how DEA set the
23 quotas?
24 A. No, that would be a Karen
25 Harper question.

Page 67

1 Q. But you would agree that it's
2 very important to comply with that quota
3 system?
4 A. Oh, yes.
5 Q. So we previously spoke about
6 diversion.
7 Do you recall that?
8 A. Yes.
9 Q. And is it your understanding
10 that Mallinckrodt products were being
11 diverted?
12 A. Is it my understanding?
13 Not that I'm aware of. Just
14 from what -- I guess what I've heard from the
15 news.
16 Q. Well, but you've seen news
17 reports indicating that Mallinckrodt products
18 have been diverted; is that fair?
19 A. Yes. Yes.
20 Q. And do you recall what those
21 news reports said?
22 A. No, not really.
23 Q. But your understanding from
24 these news reports is that Mallinckrodt
25 products were being diverted and they were

Page 68

1 being abused; is that fair?
2 A. Correct.
3 Q. Are you familiar with the term
4 "Ms"?
5 A. Ms?
6 Q. Ms.
7 A. No, I'm not.
8 Q. Okay. What about "Mollies"?
9 A. Mollies?
10 I've heard of them, but I don't
11 know specifically what they are.
12 Q. Okay. Are you familiar -- are
13 you familiar with any terms or any references
14 to Mallinckrodt products with respect to
15 being street drugs?
16 A. No.
17 Q. So given that Mallinckrodt
18 products were being diverted and they were
19 being abused, are there any additional steps,
20 looking back in hindsight, that you feel
21 Mallinckrodt should have taken?
22 A. Well, I just want to say that
23 if you remember where we were in the chain of
24 manufacturing, if we're talking about bulk at
25 this time -- are we talking about 2007? Are

Page 69

1 we talking generic? What time frame?
2 Q. Let's start with dosage
3 products and then we can go to bulk.
4 A. Okay. Okay.
5 Keep in mind that the generic
6 business, we were -- you know, we had our own
7 regulations in place of meeting the DEA
8 requirements, plus we developed our
9 suspicious order monitoring program, which
10 was another step of identifying orders that
11 may have been out of order or suspicious
12 quantities.
13 And when we sold those, sold
14 our product, they went to distributors who
15 were supposed to have their own suspicious
16 order monitoring programs in place, and then
17 they sold to druggists and then to physicians
18 and then to the end user.
19 So there was a -- quite a
20 number of people in between Mallinckrodt and
21 the end user, so I would say that we did
22 our -- our due diligence in trying to keep
23 diversion from happening.
24 Q. And when you say "due
25 diligence," what do you mean by that?

<p style="text-align: right;">Page 70</p> <p>1 A. By -- by meeting the 2 requirements of the DEA. 3 Q. And so it was very important to 4 you that Mallinckrodt meet these DEA 5 requirements? 6 A. I would say it's probably the 7 most important thing that we did. 8 Q. And this view was widely shared 9 at the company; is that correct? 10 A. Yes, it was. 11 I will add that when we were 12 developing our suspicious order program, that 13 that was rolled out to our marketing people 14 and also our sales force on what our 15 requirements were and what their part would 16 be going forward in helping us on -- on 17 controlling any -- any possible suspicious 18 orders or peculiar orders as we -- it became 19 known as later on. 20 Q. How did you know that your 21 suspicious order monitoring program was 22 effective? 23 A. We did not have one suspicious 24 order while I was doing the job. 25 Q. And when you say you did not</p>	<p style="text-align: right;">Page 72</p> <p>1 particular product that the order was for, 2 and I would ask them if they knew why all of 3 a sudden we were having a peculiar order from 4 that customer. 5 And a peculiar order, again, 6 would be unusual quantity from what they have 7 bought in the past over a period of time 8 based upon the log rhythms {sic} we set in 9 place in our computer system. 10 If they didn't know, my next 11 step would be going to the salesperson and 12 asking them. 13 Q. And so when you say that you 14 didn't have any suspicious orders, though, 15 what do you mean -- what do you mean by that? 16 A. Suspicious order is one that 17 would be -- where there is possible -- where 18 we could not identify for whatever -- what 19 reason the customer was ordering more than 20 what they had in the past. That would become 21 a suspicious order. And we report that to 22 Karen Harper and her group, who would then 23 report it to the DEA. 24 Q. And so I just want to make sure 25 I understand what your testimony is.</p>
<p style="text-align: right;">Page 71</p> <p>1 have one suspicious order while you were 2 doing the job, what do you mean by that? 3 A. Well, just to talk a little bit 4 about the suspicious order program that we 5 developed, an order would be flagged every 6 day -- an order could be flagged on a daily 7 basis as being suspicious or peculiar, as we 8 called it, and what that is, is just a stage 9 that we went through. 10 If an order was flagged as 11 being peculiar, it was during my time, my job 12 or responsibility to talk to marketing or our 13 customer service reps, who would be the first 14 people that I would talk to because they were 15 in tuned to our customers and what their 16 order needs were, and they would know if 17 there was anything unusual as far as a 18 distributor picking up a new customer that 19 they hadn't had before that they would now 20 need increased material to supply. 21 And if our CSR did not have 22 a -- an answer to why the customer was 23 ordering more, I would go to the product 24 manager, or business manager, whatever they 25 were being called at the time, who had that</p>	<p style="text-align: right;">Page 73</p> <p>1 Are you saying that because 2 none of your customers ever submitted a 3 suspicious order to you, that your suspicious 4 order monitoring program was effective? 5 MR. TSAI: Object to the form. 6 THE WITNESS: I'm saying that 7 during the time that I was running the 8 program and working the program that 9 we did not have a suspicious order. 10 QUESTIONS BY MR. KAWAMOTO: 11 Q. And when you say you "did not 12 have a suspicious order," that means that you 13 didn't identify any orders that were 14 suspicious? 15 A. We identified orders that were 16 peculiar, but we could explain them and did 17 not go to the point of being a suspicious 18 order. 19 Q. And I guess my question is, I 20 mean, you've indicated that you could explain 21 all of your peculiar orders. 22 How do you know that -- that 23 your explanations were, in fact, correct? 24 A. Because in identifying the -- 25 why the order was being determined being</p>

Page 74

1 peculiar, we had a legitimate explanation of
2 why the order was larger or peculiar from
3 what it had been in the past, increased
4 sales, a new customer was coming aboard that
5 the customer of ours had gotten. They were
6 explainable orders is what I'm saying. So,
7 therefore, they went to peculiar order to
8 legitimate order.
9 Q. And the explanation you were
10 getting, though, was ultimately being
11 provided by the customer; is that accurate?
12 A. By the -- by the -- well, from
13 the salesman or from marketing or the product
14 manager in dealing with the customer.
15 Q. So they would get the
16 information from the customer --
17 A. Correct.
18 Q. -- and relay it to you?
19 A. At that -- yes.
20 Q. Was there ever a circumstance
21 why a customer lied to one of your sales
22 reps?
23 A. I don't know that.
24 Q. If the customer lied to your
25 sales rep, then, in fact, the order would not

Page 75

1 be legitimate; is that correct?
2 MR. TSAI: Object to the form.
3 Go ahead.
4 THE WITNESS: That's possible,
5 but what I'm saying that from when I
6 was working at, we were -- we were
7 satisfied with explanations that we
8 were receiving from our sales force
9 and the marketing folks why the order
10 was legitimate.
11 QUESTIONS BY MR. KAWAMOTO:
12 Q. Are you familiar with the
13 compensation scheme for your sales force?
14 A. No, I'm not.
15 Q. Do you know if their bonus was
16 dependent in any way on the number of sales
17 they made?
18 A. Well, I would guess that sales
19 would be involved, but keep in mind that the
20 sales force were very aware of the DEA
21 compliance that Mallinckrodt enforced and
22 they knew it could lead to firing or us
23 losing our license to manufacture and sell.
24 So it was a high priority for us over and
25 beyond sales.

Page 76

1 Q. Was the sales force's
2 compensation based upon their -- strike that.
3 Was the sales force's
4 compensation in any way based upon their
5 compliance with the DEA regulations?
6 MR. TSAI: Object to the form.
7 THE WITNESS: I can't -- I
8 can't answer that. I don't know.
9 (Mallinckrodt-Rausch Exhibits 1
10 and 2 marked for identification.)
11 QUESTIONS BY MR. KAWAMOTO:
12 Q. I would like to mark this as
13 Exhibit 1.
14 And actually this Exhibit 1
15 goes in connection with Exhibit 2, so I'm
16 going to mark that as well.
17 So. Mr. Rausch, I've handed
18 you two exhibits. The first one is an e-mail
19 chain and it bears the Bates number
20 MNK-T1_273559. That's Exhibit 1.
21 And then I've also provided you
22 with an exhibit marked Exhibit 2. This is a
23 letter from the DEA, and it's dated
24 September 27, 2006, and it bears a Bates
25 number MNK-T1_273563.

Page 77

1 A. Okay.
2 Q. Do you have both exhibits, sir?
3 A. I do.
4 Q. So directing your attention to
5 the e-mail if the very top of the e-mail
6 chain?
7 A. Which -- on Exhibit 1?
8 Q. On Exhibit 1.
9 A. Okay.
10 Q. Do you see the second paragraph
11 that says, "Please note that Vince Kaiman and
12 I had a conversation"?
13 A. Yes.
14 Q. Okay. And this is an e-mail
15 from Karen Harper, but she's indicating that
16 she shared a DEA letter with you.
17 Do you see that?
18 A. Correct.
19 Q. Okay. And Exhibit 2 I believe
20 is that letter.
21 A. I want to look at that now?
22 Q. Yes. Could you look at that?
23 A. Okay.
24 Q. Do you recall Karen Harper
25 sharing this letter from you -- with you?

Page 78

1 A. I don't.
2 Q. Okay.
3 A. Just because I don't remember
4 seeing it. It's been a long time.
5 Q. Sure.
6 But do you recall receiving
7 this letter at some point?
8 A. I don't recall it, but that
9 doesn't mean I didn't receive it.
10 Q. Okay. Do you recall ever
11 reviewing a letter like this?
12 A. Yes.
13 Q. And why did you review this
14 letter?
15 A. Can I --
16 Q. Absolutely.
17 A. Can I take a look at it?
18 Q. Yes. Actually, why don't you
19 review that letter and let me know when
20 you're ready.
21 A. Okay. Okay.
22 Q. So directing your attention to
23 the second page of this letter, it bears the
24 Bates number 273564, do you see the third
25 paragraph from the bottom? It starts, "Thus

Page 79

1 in addition."
2 A. Okay.
3 Q. And can you read that paragraph
4 into the record for me?
5 A. "Thus, in addition to reporting
6 all suspicious orders, a distributor has a
7 statutory responsibility to exercise due
8 diligence to avoid filling suspicious orders
9 that might be diverted into other than
10 legitimate, medical, scientific and
11 industrial channels. Failure to exercise
12 such due diligence could, as circumstances
13 warrant, provide a statutory -- statutory
14 basis for revocation or suspension of the
15 distributor's registration."
16 Q. Now, did you understand that
17 that legal requirement also applied to
18 Mallinckrodt as a manufacturer?
19 MR. TSAI: Object to the form.
20 Go ahead.
21 THE WITNESS: Yes.
22 QUESTIONS BY MR. KAWAMOTO:
23 Q. Okay. And then do you see in
24 the paragraph beneath that, it says, "A
25 distributor may not simply rely on the fact

Page 80

1 that the person placing the suspicious order
2 is a DEA registrant and turn a blind eye to
3 the suspicious circumstances."
4 Do you understand that to also
5 require -- also apply to Mallinckrodt as a
6 manufacturer?
7 A. Yes.
8 Q. Okay. Then turning to page 3
9 of the memo. It says, "Circumstances that
10 might be indicative of diversion." It
11 identifies four -- four circumstances.
12 Would you agree that those
13 circumstances are ones that are indicative of
14 diversion?
15 A. Certain pharmacies have engaged
16 in dispensing controls.
17 Those are four circumstances
18 that could lead to diversion, yes.
19 Q. And so if a distributor -- if a
20 distributor's order fell within one of these
21 four circumstances, you would agree that that
22 is potentially a suspicious order, would you
23 not?
24 A. Peculiar order, yes.
25 Q. Then below that, there's --

Page 81

1 there's a paragraph below that with ten
2 questions.
3 Do you see that?
4 A. Yes.
5 Q. So the first question is:
6 "What percentage of the pharmacy's business
7 does dispensing controlled substances
8 constitute?"
9 Would you agree that that is
10 important information to have and evaluate
11 whether an order is suspicious?
12 A. For the distributor?
13 Q. Yes.
14 A. I would say yes.
15 Q. And then if you were to change
16 this question so that it be what percentage
17 of the distributor's business does dispensing
18 controlled substances constitute, would you
19 agree that that's important information for
20 Mallinckrodt to have with respect to its
21 customer?
22 A. Yes.
23 Q. Okay. And so for number 2 it
24 says: "Is the pharmacy compliant with the
25 laws of every state in which it is dispensing

Page 82

1 controlled substances?"

2 If you were to substitute, you

3 know, one of Mallinckrodt's customers in for

4 "pharmacy," would you agree that's important

5 information for Mallinckrodt to have?

6 A. Yes.

7 Q. Okay. So looking at these -- I

8 guess the remaining ten questions, in an

9 effort to try to truncate things, would you

10 agree that all of these questions, as applied

11 to Mallinckrodt's customers, are important

12 information for Mallinckrodt to have in

13 assessing whether an order is peculiar?

14 MR. TSAI: Object to the form.

15 THE WITNESS: No, not all of

16 them would apply to our business of

17 selling to the distributors.

18 QUESTIONS BY MR. KAWAMOTO:

19 Q. Okay. Which ones would not

20 apply?

21 A. Well, does the pharmacy fill

22 prescriptions issued by practitioners based

23 solely on an online questionnaire without a

24 medical exam or bona fide doctor-patient

25 relationship.

Page 83

1 Do you want me to go through

2 all of them and tell you which ones I don't

3 think would apply?

4 Q. Yes, I think that would be

5 helpful.

6 So I have number 5 and then...

7 A. Number 3.

8 Q. Okay.

9 A. Number 4.

10 Number -- well, number 8 is

11 something that we wouldn't -- wouldn't be

12 part of.

13 Number 9.

14 Number 10.

15 Q. And your basis for identifying

16 these is because Mallinckrodt doesn't do

17 business directly with pharmacies; is that

18 correct?

19 A. Correct.

20 Q. Okay. Does Mallinckrodt do

21 business with retail pharmacies, though? For

22 example, you know, CVS or Walgreens?

23 A. With chains.

24 Q. With pharmacy chains?

25 A. Right.

Page 84

1 Q. And so if a pharmacy chain fell

2 into any one of these six categories,

3 wouldn't that be of concern to Mallinckrodt?

4 MR. TSAI: Object to the form.

5 THE WITNESS: I would guess so.

6 QUESTIONS BY MR. KAWAMOTO:

7 Q. Okay. So, for example, if you

8 had a retail pharmacy that was soliciting

9 buyers of controlled substances via the

10 Internet or is a pharmacy associated with the

11 Internet that solicits orders for controlled

12 substances, that would be of concern to

13 Mallinckrodt, would it not?

14 A. Yes.

15 Q. And modifying that question, if

16 you were -- if one of your distributors was

17 doing business with, for example, a pharmacy

18 or an Internet site affiliated with the

19 pharmacy offering to facilitate the

20 acquisition of a prescription for a

21 controlled substance from a practitioner with

22 whom the buyer has no preexisting

23 relationship, wouldn't that be of concern to

24 you?

25 A. We sold to the distributors,

Page 85

1 not -- your question was about the

2 distributor.

3 Q. Well, no, I'm sorry. Let me

4 rephrase that.

5 My question is now about the

6 distributors' customers.

7 A. Okay.

8 Q. So you've got a list here of

9 ten essentially -- would it be fair to call

10 these red flags?

11 A. Yes.

12 Q. Okay. So you've got a

13 question -- you've got a list here of ten red

14 flags.

15 If a distributor is doing

16 business with a pharmacy that raises one or

17 more red flags, wouldn't that be of concern

18 to Mallinckrodt?

19 MR. TSAI: Object to the form.

20 THE WITNESS: Well, it would be

21 a red flag for the distributor who

22 also has a suspicious order monitoring

23 program that should be in place.

24 Okay.

25 We were -- we were not

Page 86

1 monitoring our customers' customer at
 2 this time. We were asked to -- to
 3 monitor our customers or build a
 4 report -- a suspicious order program
 5 on our customers.
 6 QUESTIONS BY MR. KAWAMOTO:
 7 Q. And you said you're not
 8 monitoring them at this time.
 9 A. Well, okay. We weren't
 10 monitoring them. When I had -- this is back
 11 in 2007. When I was in -- or in 2006,
 12 actually. When I didn't -- I was in the bulk
 13 area, not in the dosage area.
 14 But our program was based upon
 15 the customers that we were selling to, not
 16 who our customers' customers were selling to.
 17 We didn't have that information available to
 18 us at that time.
 19 Q. And do you know if --
 20 A. Am I making myself clear?
 21 Q. Well, I think so, but I want to
 22 make sure I understand what you're saying.
 23 A. Okay.
 24 Q. So with respect to the bulk
 25 area, which is prior to 2007 -- which is

Page 87

1 prior to 2007 --
 2 A. Uh-huh.
 3 Q. This letter is dated 2006.
 4 You're saying that from -- from
 5 the standpoint of the bulk narcotics
 6 business --
 7 A. Yes.
 8 Q. -- you were not looking at your
 9 customers' customer; is that accurate?
 10 A. That's correct.
 11 Q. Okay.
 12 A. And keep in mind, back then, we
 13 were sending a monthly letter to the DEA
 14 office, which I think I talked about earlier
 15 in our conversation. That was the
 16 requirement of the DEA at that time in 2006,
 17 and I believe into 2007, and then the DEA was
 18 telling us through our compliance group where
 19 we were getting the information like this and
 20 in talks with her that the letter was no
 21 longer needed. They didn't want to see the
 22 letter. They wanted us to start developing a
 23 program, which we would call our -- ongoing
 24 our suspicious order monitoring program,
 25 which we worked on for a period of time and

Page 88

1 was put in place in the end of 2008.
 2 So from the bulk business, we
 3 were monitoring our customers, not their
 4 customers.
 5 Q. But Mallinckrodt had the
 6 capability of monitoring your customers'
 7 customers, did it not?
 8 A. On the bulk business?
 9 No, not that I am aware of.
 10 Q. Did it have the ability to do
 11 so on the dosage side?
 12 A. From a customer service
 13 perspective, no.
 14 Q. Well, you indicated a customer
 15 service perspective. I guess I would ask the
 16 question --
 17 A. We did not have the resources
 18 to identify who our customer -- who our
 19 customer were selling to.
 20 Q. And when you say "resources,"
 21 you're talking about you didn't have enough
 22 employees; you did not have enough staff?
 23 A. No, we didn't have the data
 24 information available to us, that I'm aware
 25 of.

Page 89

1 Q. On the -- either on the dosage
 2 side or on the bulk side?
 3 A. Well, are we bouncing back and
 4 forth?
 5 On the bulk side, we did not.
 6 Q. Okay. So on the bulk side, you
 7 did not have -- you did not have the data
 8 that would allow you to know who your
 9 customers' customer was?
 10 A. Right.
 11 Q. Now, turning to the dosage
 12 side --
 13 A. Which I did not have at that
 14 time.
 15 Q. Understood.
 16 But turning to the dosage side
 17 prior to 2007 --
 18 A. Right.
 19 Q. -- did Mallinckrodt -- are you
 20 aware -- well, strike that.
 21 Did Mallinckrodt have the
 22 ability to monitor its customers' customer?
 23 A. I was not aware if it was or
 24 not.
 25 Q. And when you say you're "not

Page 90

1 aware," is that -- strike that.
2 You don't know one way or the
3 other; is that fair?
4 A. Correct.
5 Q. Would Cathy Stewart know?
6 MR. TSAI: Object to the form.
7 THE WITNESS: I can't answer
8 that. I don't know what Cathy would
9 know about it.
10 QUESTIONS BY MR. KAWAMOTO:
11 Q. Okay. But in any event,
12 Mallinckrodt was not monitoring its
13 customers' customer on the dosage side prior
14 to 2007?
15 A. As far as I know, they were
16 not. They were -- they were doing the same
17 thing the bulk side was doing.
18 Q. Would you agree, though, that
19 from a standpoint of diversion control and
20 diversion prevention, it would be helpful to
21 know your customers' customer?
22 A. I can't answer that. I
23 don't -- I don't know the answer to that from
24 a diversion.
25 I mean, keep in mind I want to

Page 91

1 reiterate that we were not the only player in
2 this -- in this closed loop where we were
3 selling to our customer, our customer was
4 supposed to be monitoring their customer all
5 the way down to the pharmacist and the
6 doctor.
7 Q. Well, but I have a slightly
8 different question, which is: You know a
9 distributor is distributing to, let's say,
10 Internet pharmacies that are just filling
11 prescriptions, you know, over the Internet,
12 it's soliciting orders over the Internet, and
13 that's an area of concern, that's one of the
14 red flags raised in this 2006 letter, is it
15 not?
16 A. Yes.
17 Q. Okay. So you've got a
18 distributor and you know that distributor is
19 doing business with those types of
20 pharmacies; isn't that of concern to
21 Mallinckrodt?
22 A. I think that's one of the
23 reasons we put in our program on the
24 deviation of orders that were coming from our
25 customers to show if there was a suspicious

Page 92

1 order there. We couldn't tell who they were
2 selling to at that time.
3 If you're asking me did I
4 think -- do I feel that knowing our
5 customers' customer would benefit
6 Mallinckrodt or benefit the diversion? It's
7 possible, but I can't answer that for sure.
8 Q. Well, if Mallinckrodt, though,
9 had the ability to monitor its customers'
10 customer, would you --
11 A. Is that hypothetically?
12 Q. Hypothetically.
13 If they had the ability to do
14 that, would you agree that it would have been
15 helpful to diversion control for them to do
16 so?
17 MR. TSAI: Object to the form.
18 THE WITNESS: Yes, it would be
19 helpful.
20 QUESTIONS BY MR. KAWAMOTO:
21 Q. Okay. Do you believe it should
22 have been required?
23 A. I can't answer that. We were
24 meeting the requirements that I felt were in
25 place at the time.

Page 93

1 That's a -- that's a Karen
2 Harper question.
3 Q. So turning now -- I'm going to
4 focus your attention on two other -- two more
5 exhibits, and so I'm marking these in tandem
6 as Exhibit 3 and as Exhibit 4.
7 (Mallinckrodt-Rausch Exhibits 3
8 and 4 marked for identification.)
9 QUESTIONS BY MR. KAWAMOTO:
10 Q. This is Exhibit 3 and it bears
11 the Bates number MNK-T1_419874.
12 And while I'm labeling things,
13 I'm going to also label Exhibit 4. This is a
14 DEA letter, and it bears a Bates number
15 MNK-T1_421084.
16 A. Okay. You want me to read
17 this, or you want just --
18 Q. Actually, I just have a few
19 quick questions on this cover e-mail.
20 A. Okay.
21 Q. But it is an e-mail to -- from
22 Karen Harper to Cathy Stewart.
23 Do you see the second e-mail
24 that's dated -- the second e-mail from the
25 top dated March 12, 2008?

Page 94

1 A. Okay. Yes.
 2 Q. It references attached
 3 information that Karen had sent to you and
 4 Michael Phenev.
 5 Who is Michael Phenev?
 6 A. Michael Phenev was my boss at
 7 the time.
 8 Q. And I believe the
 9 attachments on -- the attachment to this
 10 e-mail is this December 27, 2007 letter.
 11 So if I could -- well, do you
 12 recall Karen Harper sending you this -- this
 13 letter?
 14 A. No, I don't.
 15 Q. Okay. Actually, I'm sorry, if
 16 you look at the very bottom of the page,
 17 there's an e-mail from Karen Harper dated
 18 January 4, 2008, and you are -- you are one
 19 of the cc's.
 20 Do you see that?
 21 A. Yes.
 22 Q. Okay. Do you recall Karen
 23 Harper sending you this e-mail?
 24 A. No, it's been --
 25 Q. Do you have any reason to doubt

Page 95

1 that she sent you this e-mail?
 2 A. No, I don't.
 3 Q. Okay. Could you please review
 4 the December 27, 2007 letter? I believe
 5 that's Exhibit 4.
 6 A. Okay.
 7 Q. Okay. So do you recall
 8 reviewing this letter when you were employed
 9 by Mallinckrodt?
 10 A. I recall it.
 11 Q. Okay. So directing your
 12 attention to the third paragraph from the top
 13 of the first page of the letter --
 14 A. Okay.
 15 Q. -- it said, "The regulation
 16 also requires that the registrant inform the
 17 local DEA division office of suspicious
 18 orders when discovered by the registrant."
 19 A. Okay.
 20 Q. "Filing a monthly report of
 21 completed transactions, e.g., an excessive
 22 purchase report or high unit purchases, does
 23 not meet the regulatory requirement to report
 24 suspicious orders.
 25 "Registrants are reminded that

Page 96

1 the responsibility does not end merely with
 2 the filing of a suspicious order report.
 3 Registrant must conduct an independent
 4 analysis of suspicious orders prior to
 5 completing a sale to determine whether the
 6 controlled substances are likely to be
 7 diverted from legitimate channels."
 8 Do you understand that
 9 language?
 10 A. Yes.
 11 Q. And is that -- is that a
 12 correct statement of Mallinckrodt's
 13 responsibilities under the law?
 14 A. Yes.
 15 Q. Okay. Further on down it
 16 states, "The regulation specifically states
 17 that suspicious orders include orders of an
 18 unusual size, orders deviating substantially
 19 from a normal pattern, and orders of an
 20 unusual frequency. These criteria are
 21 disjunctive and are not all inclusive."
 22 Do you see that?
 23 A. Yes.
 24 Q. And do you understand what that
 25 means?

Page 97

1 A. Yes.
 2 Q. And is that an accurate
 3 statement of what a suspicious order is?
 4 A. Yes.
 5 Q. Okay.
 6 A. And then some.
 7 Q. Okay. At the very bottom of
 8 that paragraph it says, "The size of an order
 9 alone, whether or not it deviates from a
 10 normal pattern, is enough to trigger the
 11 registrant's responsibility to report the
 12 order as suspicious.
 13 "The determination of whether
 14 an order is suspicious depends not only on
 15 the ordering patterns of the particular
 16 customer but also on the patterns of the
 17 registrant's customer base and the patterns
 18 throughout the relevant segment of the
 19 regulated industry."
 20 Do you see that statement?
 21 A. I do.
 22 Q. And do you agree with it?
 23 A. Yes.
 24 Q. And so you understood this to
 25 be an accurate statement of Mallinckrodt's

<p style="text-align: right;">Page 98</p> <p>1 legal responsibilities with respect to 2 suspicious orders? 3 A. From the bulk side, which is 4 where I was at this time, this was where we 5 started, from what I remember. Our St. Louis 6 field office did not want to receive the 7 monthly report any longer. Okay. 8 And we were instructed -- Karen 9 Harper and Michael Pheney and some other 10 folks put together a team of people to come 11 up with a more robust suspicious order 12 monitoring program, which included myself, 13 Cathy. Karen Harper oversaw it, but she 14 didn't come to all the meetings. We had a 15 few IT people that was involved, to come up 16 with a more robust ordering -- suspicious 17 order monitoring program that would identify 18 orders as being peculiar as the orders came 19 through. 20 This was developed over time 21 period of like 2000 -- in the 2000-2008 time 22 period and put in place. 23 Q. And this -- I guess you would 24 call -- 25 A. This was kind of the precursor</p>	<p style="text-align: right;">Page 100</p> <p>1 words, this was a floor, not a ceiling? 2 A. Correct. 3 Q. Okay. But it was -- it was 4 critically important to Mallinckrodt that its 5 enhanced SOM program meet, at a minimum, the 6 requirements in this letter? 7 A. Yes. 8 Q. Okay. And so directing your 9 attention to page 2, it says, "Registrants 10 that rely on rigid formulas to define whether 11 an order is suspicious may be failing to 12 detect suspicious orders. For example, a 13 system that identifies orders as suspicious 14 only if the total amount of a controlled 15 substance ordered during one month exceeds 16 the amount ordered the previous month by a 17 certain percentage or more is insufficient." 18 And so what is your 19 understanding of what that requirement is? 20 A. Well, I think what they're 21 saying is that it shouldn't be based on just 22 what the previous month was -- what -- what 23 previous month order might have been. Okay. 24 They're saying is that they 25 want you to take a look at an ongoing -- what</p>
<p style="text-align: right;">Page 99</p> <p>1 for that -- this kind of got the motion -- 2 wheels in motion for getting that done. 3 Q. So I take it -- and that's what 4 I think you previously referred to as your 5 enhanced suspicious order monitoring -- 6 A. Correct. 7 Q. -- program, your enhanced SOM 8 program? 9 A. Yes. 10 Q. And you would agree with me 11 that that enhanced program was required to 12 meet all of the requirements set forth in 13 this letter, would you not? 14 A. Not only what was in this 15 letter -- keep in mind the DEA did not tell 16 us what should be in our program. They 17 never -- they didn't tell us whether it was 18 correct. They didn't want to see a program. 19 They just told us that, "These are some of 20 the things that we wanted to see in your 21 program." 22 We did this stuff and included 23 some other things that they thought were 24 important. 25 Q. Okay. So this -- in other</p>	<p style="text-align: right;">Page 101</p> <p>1 I'll call a floating month period, like I 2 described earlier to you, a rolling time 3 period. So it wasn't from calendar year. It 4 was like January to January, February to 5 February, so it kept moving depending on -- 6 so if you were in April, it was looking at 7 orders that were placed from March to March, 8 okay. 9 Q. Now, it also says that 10 "Registrants that rely on rigid formulas to 11 define whether an order is suspicious may be 12 failing to detect suspicious orders." 13 A. That's exactly what I'm trying 14 to describe to you right there. They're not 15 saying don't look at what they ordered just 16 the previous month. Look at what they've 17 done over the previous 12 months or -- and in 18 our case, we said, okay, we're going to look 19 at a 12-month roving {sic} period of time. 20 Q. Okay. Doesn't this also tell 21 you though that if all you're doing is 22 relying on a rigid formula, on a numeric 23 formula, that is also insufficient? 24 MR. TSAI: Object to the form. 25 THE WITNESS: Yeah, and that's</p>

<p style="text-align: right;">Page 102</p> <p>1 what I'm trying to explain to you. 2 Not only did we have this, what 3 they're saying -- they say ordered 4 during one-month period exceeds the 5 amount ordered, that was rigid, that's 6 what they considered rigid. Okay. 7 What they were saying, don't 8 rely on what they just ordered the 9 previous month, that's what they 10 considered rigid. 11 So the rolling months was not 12 rigid. Okay. 13 We only -- we not only did 14 rolling months, but we went in 15 frequency over a period of time. We 16 not only looked at a particular size, 17 and I'm -- of a bulk product, and this 18 also applies to the dosage because I'm 19 thinking of dosage. Because we had 20 different sizes of the same product. 21 We would look at the family, 22 okay, meaning combining all the 23 products within, let's say, 24 hydrocodone, we had several different 25 sizes. So we would look at the bulks</p>	<p style="text-align: right;">Page 104</p> <p>1 Indicative of Diversion." 2 I'm sorry, it's actually page 3 3 of the letter. 4 A. Okay. Page 3. 5 At the top? 6 Q. Yes. 7 A. Okay. 8 Q. You would agree that -- 9 A. Again, we're looking at 10 pharmacies, right? 11 Q. Well, we were looking at 12 "Circumstances that Might Be Indicative of 13 Diversion." 14 A. Okay. 15 Q. And so you would agree that an 16 adequate suspicious order monitoring program 17 would take into account these four 18 circumstances, would it not? 19 A. Number 2 I don't think is 20 something that would involve what we were in 21 the business of doing, ordering a limited 22 variety of controlled substances in 23 quantities disproportionate to the quantity 24 of noncontrolled medications. I -- I 25 don't -- I don't see how that applies to us.</p>
<p style="text-align: right;">Page 103</p> <p>1 of that size, okay. 2 So if they changed it up and 3 they went from a 10 by 50 to a 25 by 4 50, you know, just to -- we would -- 5 we would take the entire amount that 6 was being bought, make sure they 7 weren't buying more than what they 8 normally did. 9 So I think we did more so than 10 what the regulations were requiring. 11 QUESTIONS BY MR. KAWAMOTO: 12 Q. Now, directing your attention 13 back to Exhibit 2, do you have that in -- can 14 you put that in front of you so that -- yeah, 15 that would be the first DEA letter we looked 16 at. 17 A. Okay. 18 Q. And do you see on page 2, it's 19 got -- under the "Circumstances that Might Be 20 Indicative of Diversion," it's identifying 21 four different issues? 22 A. Page 2, you said? 23 Q. Yes. 24 A. And where at? 25 Q. "Circumstances that Might Be</p>	<p style="text-align: right;">Page 105</p> <p>1 Q. I'm sorry. 2 A. It's not something that we 3 would have been looking at. 4 Q. Well, isn't that what that -- 5 well, reading the requirement it says, 6 "Ordering a limited variety of controlled 7 substances in quantities disproportionate to 8 the quantity of noncontrolled medications 9 ordered." 10 So if a distributor was doing 11 that from you, meaning all of the -- well, 12 let me rephrase that. 13 If a retail pharmacy was only 14 ordering controlled substances from you in 15 quantities disproportionate to the quantity 16 of noncontrolled medications ordered, so 17 we're talking a retail pharmacy here -- 18 A. Okay. 19 Q. -- wouldn't that be something 20 your suspicious order monitoring program 21 should pick up on? 22 A. When you say "noncontrolled 23 medication orders," I'm not sure, 24 noncontrolled medications, what would that 25 be?</p>

<p style="text-align: right;">Page 106</p> <p>1 Q. Well, I assume it would be 2 other pharmaceuticals that were not, for 3 example, Schedule II. 4 A. Okay. 5 Again, I go back to this is 6 something that we were not -- we didn't have 7 the tools to do at that time. 8 Q. Well, but you would agree that 9 this is a circumstance that might be 10 indicative of diversion, would you not? 11 A. I suppose it could be, yes. 12 Q. And given that and given that 13 this is -- I mean, the DEA is flagging this 14 as an issue that they are concerned about, 15 wouldn't it be important for Mallinckrodt's 16 suspicious order monitoring program, 17 particularly its enhanced SOM program, to 18 take this into account? 19 A. We were -- as far as 20 pharmacies, we were selling to chain 21 pharmacies and we were shipping to -- to 22 their shipping sites, not particular 23 pharmacies. Okay. Not individual 24 pharmacies. We were selling to their 25 warehouses.</p>	<p style="text-align: right;">Page 108</p> <p>1 industrial channels may be failing to 2 maintain effective controls against 3 diversion." 4 Now, I guess to use the 5 Mallinckrodt terminology, I should be 6 substituting in "peculiar orders"; is that 7 fair? 8 A. Correct. 9 Q. Okay. So registrants that 10 routinely -- or, you know, registrants that 11 routinely report peculiar orders yet fill 12 those orders without first determining that 13 order is not being diverted into other than 14 legitimate, scientific and industrial 15 channels may be failing to maintain effective 16 controls against diversion. 17 You would agree with that 18 statement? 19 A. Yes. 20 Q. Okay. So as part of 21 Mallinckrodt's suspicious order monitoring 22 program -- 23 A. Yes. 24 Q. -- it had to make sure that it 25 did not report -- it did not identify</p>
<p style="text-align: right;">Page 107</p> <p>1 Q. But if a chain -- if a chain 2 pharmacy is only ordering Schedule II 3 substances from you, isn't that something 4 that your program ought to have taken into 5 account and registered? 6 A. If we had the resources to do 7 so, I suppose so. 8 MR. TSAI: Dean, this is a time 9 check. It's been about an hour since 10 the last break. 11 MR. KAWAMOTO: Sure. Actually, 12 why don't I finish up on Exhibit 4 and 13 then we can take a quick break. 14 QUESTIONS BY MR. KAWAMOTO: 15 Q. So page 2 of Exhibit 4, that's 16 the 2007 DEA letter. 17 A. Page -- okay. 18 Q. Page 2. 19 A. Of 4? 20 Q. Yes. 21 It says, "Lastly registrants 22 that routinely report suspicious orders yet 23 fill these orders without first determining 24 that order is not being diverted into other 25 than legitimate, medical, scientific and</p>	<p style="text-align: right;">Page 109</p> <p>1 peculiar orders and yet fill those orders 2 without first determining that the order was 3 not being diverted; is that correct? 4 A. Are you talking about -- at 5 this time period or are you talking during 6 when? Are we talking about bulk, or are we 7 talking about dosage? 8 Q. Well, let's focus on dosage 9 products. 10 A. Okay. 11 Q. And for dosage products -- 12 A. Right. 13 Q. -- prior to 2007, it would have 14 been improper for Mallinckrodt to identify a 15 peculiar order and fill that order without 16 first determining that the order was not 17 being diverted into other than legitimate, 18 medical, scientific and industrial channels; 19 is that correct? 20 A. Yes. 21 Q. Okay. And presumably in the 22 post-2007 time period under your enhanced 23 suspicious order monitoring program, it still 24 would have been improper to fill an order 25 without first investigating the order; is</p>

<p style="text-align: right;">Page 110</p> <p>1 that correct?</p> <p>2 MR. TSAI: Object to the form.</p> <p>3 THE WITNESS: Keep it in mind,</p> <p>4 like I've mentioned before, prior to</p> <p>5 2007, we were -- we were instructed by</p> <p>6 our field offices at that time, our</p> <p>7 DEA field offices, that the monthly</p> <p>8 report that we gave them was</p> <p>9 sufficient.</p> <p>10 QUESTIONS BY MR. KAWAMOTO:</p> <p>11 Q. Okay. But nevertheless, from</p> <p>12 a -- from a standpoint of --</p> <p>13 A. From a -- from -- as far as --</p> <p>14 I can only speak towards bulk because that's</p> <p>15 what I had at the time. Okay.</p> <p>16 So besides the program that we</p> <p>17 had in place, which was what the DEA required</p> <p>18 at that time, regardless of what this letter</p> <p>19 is saying, we were also monitoring our</p> <p>20 customers of any orders that we felt -- our</p> <p>21 CSRs would notify myself or Karen Harper</p> <p>22 that, "Hey, we've got an order that's more --</p> <p>23 more than what the customer normally buys,"</p> <p>24 and we would -- we identify that and turn it</p> <p>25 over to Karen Harper for her -- to discuss</p>	<p style="text-align: right;">Page 112</p> <p>1 A. Yes.</p> <p>2 Q. So with respect to both bulk</p> <p>3 and dosage products, now, with respect to</p> <p>4 both pre-2007 and post-2007, it would have</p> <p>5 been improper for Mallinckrodt to ship an</p> <p>6 order without first concluding an</p> <p>7 investigation -- well, strike that.</p> <p>8 It would have been improper for</p> <p>9 Mallinckrodt to ship a peculiar order without</p> <p>10 first concluding its investigation as to</p> <p>11 whether that order was not going to be</p> <p>12 diverted; is that accurate?</p> <p>13 MR. TSAI: Object to the form.</p> <p>14 THE WITNESS: I would say that</p> <p>15 when I had dosage at the time, that we</p> <p>16 had an agreement with Karen Harper</p> <p>17 that we didn't always have the time</p> <p>18 because orders would go out on a daily</p> <p>19 basis from when they were -- they were</p> <p>20 entered, and they -- if an order</p> <p>21 kicked out as peculiar, we didn't</p> <p>22 always have the ability to do the</p> <p>23 thorough investigation prior to the</p> <p>24 order being shipped. Okay.</p> <p>25 And we came to that conclusion</p>
<p style="text-align: right;">Page 111</p> <p>1 with the DEA.</p> <p>2 I want to keep in mind that in</p> <p>3 the bulk area in a time frame of seven days</p> <p>4 to a month would be our normal period of</p> <p>5 fulfilling an order because we manufactured</p> <p>6 all the orders make-on-order. Okay. We</p> <p>7 didn't stock bulk narcotics. We didn't have</p> <p>8 the -- the inventory to be able to stock it,</p> <p>9 so everything was made to order. And the</p> <p>10 time frame that we needed our -- was anywhere</p> <p>11 from seven days to a month. Okay.</p> <p>12 So we had -- what I'm getting</p> <p>13 at is we had plenty of time prior to the</p> <p>14 order being shipped to determine whether it</p> <p>15 was suspicious order or not.</p> <p>16 Q. Okay. But as I -- as I</p> <p>17 understand this letter to be stating, and</p> <p>18 please correct me if you have a different</p> <p>19 interpretation, what it's saying is that if</p> <p>20 you identify a peculiar order, you should not</p> <p>21 ship that order without investigating whether</p> <p>22 the order is -- whether the order is being</p> <p>23 diverted; is that accurate?</p> <p>24 A. I would say so.</p> <p>25 Q. Okay.</p>	<p style="text-align: right;">Page 113</p> <p>1 after several months of orders being</p> <p>2 placed through our system and we did</p> <p>3 not have any suspicious orders. What</p> <p>4 we had -- had any suspicious orders,</p> <p>5 so we felt comfortable that we could</p> <p>6 go ahead and ship the order.</p> <p>7 And the reason why we were not</p> <p>8 able to always thoroughly investigate</p> <p>9 the order prior to it shipping was,</p> <p>10 one, we didn't have the information</p> <p>11 available from the CSR, our first</p> <p>12 contact, okay. They didn't know why</p> <p>13 this is -- this order is being placed</p> <p>14 for -- unusual order was being placed.</p> <p>15 Secondly, we would go to the</p> <p>16 business manager for that product. If</p> <p>17 that business manager didn't know why</p> <p>18 there was an unusual order being</p> <p>19 placed, we would then go to the</p> <p>20 salesperson. This all took time</p> <p>21 because these people aren't always</p> <p>22 available to get back to us. Okay.</p> <p>23 And we felt comfortable enough</p> <p>24 through our -- through this program</p> <p>25 being in place for several months</p>

Page 114

1 before we went to that that we -- we
2 could continue to investigate that
3 order because that order was going to
4 a distributor who also had a program
5 in place for suspicious orders, so we
6 knew that we could get the product
7 back or stop it if need be.
8 QUESTIONS BY MR. KAWAMOTO:
9 Q. So in certain circumstances
10 then, Mallinckrodt would ship peculiar orders
11 without completing its investigation as to
12 whether that order might be diverted into
13 other than legitimate, medical, scientific or
14 industrial channels; is that correct?
15 MR. TSAI: Objection. Vague as
16 to time.
17 Go ahead.
18 THE WITNESS: Yes, we -- on
19 rare circumstances where we didn't
20 want to hold up the order because of
21 people needing for legitimate reasons,
22 medical needs, we didn't want to hold
23 up the order, but we continued to go
24 through the process of identifying
25 whether it was legitimate or not.

Page 115

1 And I can say that from the
2 time period that I have it, we did not
3 have a suspicious order.
4 QUESTIONS BY MR. KAWAMOTO:
5 Q. Did you ever inform DEA that
6 you were doing this?
7 A. Yes.
8 Well, let me say we informed
9 our DEA compliance person, Karen Harper, and
10 she was in agreement to that.
11 Q. But did you ever inform the
12 Drug Enforcement Administration?
13 A. I did not talk to the Drug
14 Enforcement Agency myself.
15 Q. Do you know if Karen Harper
16 informed the Drug Enforcement Administration?
17 A. I don't know what Karen Harper
18 did.
19 Q. So you have no basis to believe
20 that the DEA felt that this was an acceptable
21 practice?
22 A. I would say, as well as I know
23 Karen Harper and how she dealt with the DEA,
24 she kept them informed of what we were doing.
25 She would not -- she would not do anything

Page 116

1 without their blessing.
2 Q. Did Karen Harper ever tell you
3 that the DEA had signed off on this
4 agreement?
5 A. No.
6 Q. Okay. And when you say that
7 you had an agreement with Karen Harper, what
8 do you mean by that?
9 A. I asked her, based upon the
10 circumstances that I described, if it was
11 okay to do this, and she agreed to it.
12 Q. Now, was this agreement
13 memorialized in writing?
14 A. I believe there was an e-mail.
15 Q. Okay. Was this agreement
16 memorialized in any formal policy put out by
17 Mallinckrodt?
18 A. Not that I'm aware of.
19 Q. So this agreement then would
20 not be included in whatever written policy
21 you had regarding your enhanced suspicious
22 order monitoring program, would it?
23 A. I don't remember.
24 MR. KAWAMOTO: Okay. Do you
25 want to take a break now, Rocky?

Page 117

1 MR. TSAI: Let's take a break,
2 yeah.
3 VIDEOGRAPHER: We're going off
4 the record at 11:34 a.m.
5 (Off the record at 11:34 a.m.)
6 VIDEOGRAPHER: We're back on
7 the record at 11:49 a.m.
8 QUESTIONS BY MR. KAWAMOTO:
9 Q. So, Mr. Rausch, directing you
10 to Exhibit 4 again. It's a 2007 DEA letter.
11 Do you have that in front of
12 you?
13 A. Yes.
14 Q. So looking on the back page on
15 the top paragraph -- and we've discussed this
16 briefly during the last session.
17 A. Okay.
18 Q. Do you see the top paragraph
19 where it says, "Registrants that rely on
20 rigid formulas to define whether an order is
21 suspicious may be failing to detect
22 suspicious orders."
23 A. Yes.
24 Q. And your interpretation of that
25 requirement is that you couldn't just rely on

Page 118

1 the month before; is that accurate?

2 A. Well, I think that's what

3 they're -- they're saying here. For example,

4 a system that identifies orders as suspicious

5 only if the total amount of controlled

6 substance ordered during one month exceeds

7 the amount ordered the previous month.

8 Q. Okay. And so --

9 A. That -- that I interpret as

10 being rigid.

11 Q. And so it would be improper to

12 just look at one month, but if you were to

13 look at the past two months, that would be

14 okay; is that your interpretation?

15 A. No. No.

16 Well, what I'm saying is --

17 what we -- what we did is we looked at a

18 12-month roving {sic} period of time, as I

19 explained earlier, where we not only looked

20 at the previous month and the month before

21 that and six months before that, but a year's

22 basis.

23 So if they placed an order, for

24 example, in April, okay, what we looked at

25 were orders that had been placed from, say,

Page 119

1 March of that year, the month before, through

2 the past March of the previous year.

3 And so -- and that -- then that

4 just kept changing. If an order was placed

5 in May, we would look from April through

6 April.

7 Q. Okay.

8 A. Does that make sense?

9 Q. I believe I understand that.

10 A. Okay.

11 Q. I guess my question is so

12 your -- your understanding of what it means

13 not to rely on a rigid formula is that your

14 formula shouldn't be time limited,

15 essentially, to one month.

16 Is that -- is that what you're

17 indicating?

18 A. I think that's what my -- our

19 interpretation is what the DEA is saying

20 there. Don't just look at one -- what they

21 bought the previous month because that's not

22 going to give you a good feel for an order

23 pattern that is deviant from possibly past

24 orders.

25 Q. And what is your basis for that

Page 120

1 interpretation?

2 A. Just thought that was the

3 better approach than just looking at one

4 month.

5 And if I'm reading here, it

6 says, okay, "should not rely on rigid

7 formulas to define whether an order is

8 suspicious or not," and they give, for

9 example, a system that defines -- identifies

10 orders as suspicious only in a total amount

11 of the controlled substance ordered during

12 one month.

13 Q. Well, let me -- go ahead.

14 A. Do I understand what

15 you're asking?

16 Q. Well, let me phrase this

17 another way.

18 So you have three potential

19 options. Option one is you would have -- you

20 would base your SOM system on just look --

21 just comparing the current order to the

22 previous month's order, and your

23 understanding is that the DEA disapproved of

24 that approach.

25 A. They show that as an example.

Page 121

1 Q. The other approach would be,

2 you know, what you did -- what Mallinckrodt

3 did, which is to compare the current order to

4 the average of the past 12 months on a

5 rolling basis; is that accurate?

6 A. Correct. Correct.

7 Q. Another approach would be in

8 addition to looking at, you know -- in

9 addition to comparing the current order to

10 the prior 12-month order on a rolling basis,

11 you could also look at other factors. For

12 example, the factors identified in the 2006

13 letter.

14 So, you know, what are -- what

15 are they ordering relative -- how much -- or

16 how much opioids are they ordering relative

17 to other products?

18 Is there -- is there a pattern

19 with respect to, you know, how often that

20 they are -- they are providing an order that

21 would, for example, trigger the peculiar

22 order threshold?

23 Are they ordering excessive

24 quantities of controlled substances in

25 combination with, you know, an excessive

<p style="text-align: right;">Page 122</p> <p>1 quantities of lifestyle drugs?</p> <p>2 So you could have a suspicious</p> <p>3 order monitoring program that had both this</p> <p>4 formula in addition to other factors.</p> <p>5 A. Well, keep in mind --</p> <p>6 MR. TSAI: Object to the form.</p> <p>7 Go ahead.</p> <p>8 THE WITNESS: Keep in mind that</p> <p>9 as the bulk customer service rep at</p> <p>10 that time, what the DEA -- our field</p> <p>11 office was requiring is what we were</p> <p>12 supplying. We gave them what -- what</p> <p>13 we had as our criteria, which I just</p> <p>14 told you it was based upon a 12-month</p> <p>15 rolling average. They approved that</p> <p>16 and we had that system in place up</p> <p>17 until 2007, 2008, at which time they</p> <p>18 said that was no longer going to be</p> <p>19 valid. And that's when we started</p> <p>20 developing our enhanced program.</p> <p>21 So regardless of what they have</p> <p>22 here, what our requirements were at</p> <p>23 the time was was what I just told you.</p> <p>24 QUESTIONS BY MR. KAWAMOTO:</p> <p>25 Q. And do you know -- is this the</p>	<p style="text-align: right;">Page 124</p> <p>1 was a particular size, like a 25-tablet</p> <p>2 bottle versus a 50-tablet bottle, they each</p> <p>3 would be separate SKUs. So just not looking</p> <p>4 at the orders for those particular ones. If</p> <p>5 they were within what we called the same</p> <p>6 family, we would look at the total of that</p> <p>7 family.</p> <p>8 So what we wanted to make sure</p> <p>9 as far as diversion is that to keep somebody</p> <p>10 from trying to get something by us is to one</p> <p>11 month order the 50-tab bottle and then the</p> <p>12 next month order the hundred-tab bottle. So</p> <p>13 we were looking at the combined of that</p> <p>14 family, combination of that family, and that</p> <p>15 would be flagged.</p> <p>16 Irregular order patterns was</p> <p>17 added, which I think is talked about in here.</p> <p>18 A number of different things.</p> <p>19 Q. And I'm sorry, when you were</p> <p>20 talking about the 50 versus a hundred tabs --</p> <p>21 A. Right.</p> <p>22 Q. -- what you're referring to</p> <p>23 is --</p> <p>24 A. Tablet bottles.</p> <p>25 Q. Tablet bottles.</p>
<p style="text-align: right;">Page 123</p> <p>1 same system that was in place regarding</p> <p>2 dosage products for the prior -- the pre-2007</p> <p>3 time period?</p> <p>4 A. I believe so, but that's a</p> <p>5 question that I would refer to Cathy Stewart</p> <p>6 who had it at the same time.</p> <p>7 Q. Okay. And so if I understand</p> <p>8 your testimony, this formula, which was based</p> <p>9 on looking, comparing, the current order to</p> <p>10 the prior 12-month rolling period, that</p> <p>11 formula, was changed after 2007 when you took</p> <p>12 over the role of dosage products?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. And what was -- what was</p> <p>15 the change or how was it changed?</p> <p>16 A. What was our new program?</p> <p>17 Q. Yes.</p> <p>18 A. Okay. I don't remember all of</p> <p>19 the particulars, but -- because it's been a</p> <p>20 long period of time.</p> <p>21 With the input of Cathy and</p> <p>22 several other people, it was based upon not</p> <p>23 only the order quantity on a rolling average,</p> <p>24 it was based upon not -- not only on a</p> <p>25 particular SKU, what I'll call a SKU, which</p>	<p style="text-align: right;">Page 125</p> <p>1 So ordering 50 tablet bottles</p> <p>2 from one family and then ordering a hundred</p> <p>3 tablet bottles from another family --</p> <p>4 A. No, from the same family.</p> <p>5 Okay.</p> <p>6 Q. Okay.</p> <p>7 A. So let's say hydrocodone,</p> <p>8 example, let's say they came in sized bottles</p> <p>9 of 50 tablets or a hundred tablets, okay, but</p> <p>10 they all came from the same crude, okay, or</p> <p>11 what we would call family, all right.</p> <p>12 So if somebody came in and</p> <p>13 ordered 100 one month, then came back the</p> <p>14 next month and ordered 50, the computer</p> <p>15 system would keep track of that and look at</p> <p>16 it at the higher level of where that was</p> <p>17 coming from in the crude. It would look at</p> <p>18 the total combination or combined of those</p> <p>19 orders.</p> <p>20 Q. So it was essentially looking</p> <p>21 at the number of -- it was taking into</p> <p>22 account the number of pills in the dosage --</p> <p>23 A. Correct.</p> <p>24 Q. -- as opposed to just --</p> <p>25 A. Correct.</p>

Page 126

1 Q. -- you know, how many pills --
2 A. Right.
3 Q. -- or how many bottles?
4 A. Right.
5 Q. Okay. So why don't we turn
6 to -- I would like to mark as -- I believe
7 we're up to Exhibit 5.
8 (Mallinckrodt-Rausch Exhibit 5
9 marked for identification.)
10 QUESTIONS BY MR. KAWAMOTO:
11 Q. Okay. And so I've marked as
12 Exhibit 5, it's a PowerPoint. It's dated
13 June 5, 2008. Because I've got it printed in
14 native form, I'm going to read the Bates
15 number into the record. So the Bates number
16 for this is MNK-T1_2250046.
17 So, Mr. Rausch, I would like
18 you to quickly review this PowerPoint and let
19 me know when you -- when you're done.
20 A. Okay.
21 Q. So this is a PowerPoint dated
22 June 5, 2008, and its entitled "Introductory
23 Training for Field Sales."
24 Have you seen this PowerPoint
25 before?

Page 127

1 A. I believe I have.
2 Q. Okay. Did you help prepare
3 this?
4 A. No, it was prepared by Karen
5 Harper, I believe.
6 Q. Okay. But have you reviewed
7 this before?
8 A. I've seen it before.
9 Q. And did you work with Karen
10 Harper on preparing this?
11 A. No, I don't believe so.
12 Q. So turning to page 3 of the
13 PowerPoint, it says, "Mallinckrodt's
14 suspicious order procedure team."
15 A. Oh, okay.
16 Q. Do you see that page?
17 A. Yes, I do.
18 Q. Who is JoAnne Levy or Levy?
19 A. JoAnne Levy is the -- was the
20 VP of logistics.
21 Q. So did everyone else report up
22 to her?
23 A. No. Bill -- let's see.
24 Michael Pheney did. I did.
25 Cathy did. Bill Ratliff, I believe, did.

Page 128

1 John Adams didn't.
2 Karen Harper, I'm not sure if
3 she did or didn't at that time. She -- her
4 reporting relationship changed, but I don't
5 remember what the time period was.
6 Q. Okay. So at one time --
7 A. Susan Marlatt didn't.
8 Q. At one time she did report to
9 JoAnne Levy or --
10 A. I don't remember --
11 Q. Okay.
12 A. -- what her reporting
13 relationship was at that time.
14 Q. And so in terms of compliance
15 issues, the people that would have been
16 involved with the compliance side of the
17 program -- well, could you identify for the
18 people -- for me the people on this team that
19 would have been involved in the compliance
20 issues?
21 A. Well, as far as customer
22 service would be myself and Cathy. Susan
23 Marlatt from the credit and collections
24 department, they would be involved in setting
25 up the customer and doing the credit

Page 129

1 background checks on them.
2 Who else we got?
3 We all reported into -- well,
4 not all. Cathy and myself reported into
5 Michael Pheney.
6 Kimberly France, I don't
7 remember her.
8 Q. And who was responsible for
9 making sure that the program and the policies
10 complied with the DEA regulations and
11 applicable law?
12 A. That would be Karen Harper.
13 Q. Okay. Now, there are team
14 advisors listed at the bottom of the page.
15 A. Right.
16 Q. Do you know what role they
17 played?
18 A. Their role was to enforce what
19 the order monitoring procedures became --
20 rolled out. They were at a higher level.
21 This presentation was given and Jerry Moss
22 was the vice president of sales for the bulk
23 division, and Jason Jones, I'm not sure, but
24 he was over one of the sales organizations.
25 And same with Jeff Burd, he was marketing.

Page 130

1 Bob Lesnak was in sales over the methadone
 2 area, I believe, and then Eileen Spaulding,
 3 was -- again, she reported into Karen Harper.
 4 Q. And so you indicated that their
 5 role was to enforce what the monitoring
 6 procedure.
 7 So they -- did they help
 8 develop them or -- sorry?
 9 A. Well, when I -- when you say
 10 "enforce," to make sure that this was rolled
 11 out to our salespeople.
 12 And what happened here, what
 13 occurred, was every year the sales force
 14 would get together for a week-long period of
 15 time to go over different things that were
 16 going on in sales and then something like
 17 this would be rolled out by Karen during that
 18 week --
 19 Q. Okay.
 20 A. -- just to instruct them on
 21 what the new DEA regulations -- what the DEA
 22 regulations were, what we were doing as far
 23 as developing a new program, what their role
 24 was expected of them in this program, and so
 25 forth.

Page 131

1 Q. And so the person that would
 2 have been responsible for making sure that
 3 the suspicious order monitoring program
 4 complied with the DEA requirements was Karen
 5 Harper?
 6 A. She would be the -- yes.
 7 Q. And so she would have been the
 8 one that spoke to the DEA about this program?
 9 A. She probably tried -- yeah, she
 10 would notify them, but the DEA did not say
 11 one way or the other whether they liked it or
 12 they didn't approve it or disapprove it.
 13 They -- they stayed out of that.
 14 Q. Okay.
 15 A. As far as I remember.
 16 Q. Now, did --
 17 A. They didn't recommend a program
 18 and didn't say whether -- or approve programs
 19 as far as I know.
 20 Q. But if they had concerns, they
 21 would let Mallinckrodt know, wouldn't they?
 22 A. Oh, yes. Yes.
 23 Q. Did this team have team
 24 meetings?
 25 A. Yes.

Page 132

1 Q. And did someone take notes at
 2 those meetings?
 3 A. I don't remember. I don't
 4 remember.
 5 Q. Was there any type of secretary
 6 for these meetings?
 7 A. No.
 8 Q. Did this team have any central
 9 files?
 10 A. I don't remember.
 11 Most of the teams -- in this --
 12 I don't see -- let's see.
 13 Everybody was given assignments
 14 on what was needed to be done and we work on
 15 our assignments and meet on a frequent basis
 16 to see where we were as far as coming up with
 17 the new suspicious order reporting system.
 18 Q. And who was the team leader?
 19 A. I believe it was Karen.
 20 Q. So she would have been the one
 21 giving out assignments and making sure that
 22 they were completed; is that correct?
 23 A. Well, she wouldn't give out
 24 assignments. During the meeting, we would
 25 all talk about what we wanted to see, and

Page 133

1 based upon what person was involved in that
 2 particular area, they would go back and work
 3 on that.
 4 Say for IT, we asked them to
 5 take a look at -- "IT" meaning information
 6 services or computer people, okay -- we would
 7 ask them to see, you know, can this be
 8 implemented into the system, so they would go
 9 back and do their due diligence on whether
 10 that can be done.
 11 Cathy and I would be -- would
 12 take a look at, you know, what was possible
 13 on our end to get done.
 14 So everybody was given
 15 assignments and then we would come back and
 16 talk about what we had come up with or done.
 17 Q. And so -- well, strike that.
 18 Do you know when this team was
 19 first formed?
 20 A. Not the exact time frame. This
 21 was probably June of 2008. Probably earlier
 22 in that time frame since we kind of details
 23 out a little bit what we're going to be
 24 looking at. Probably early 2008, maybe late
 25 2007.

Page 134

1 Q. And was this team in existence
2 for your entire time between 2008 and 2013?
3 A. No, this was just to roll out
4 our new order monitoring system. What --
5 I -- I had control -- I had part of the
6 suspicious order monitoring program until
7 fall of 2010. Then it was turned over to
8 another group.
9 Q. Okay.
10 A. As far as being the one that
11 would follow up on peculiar orders and that.
12 Q. And in fall of 2010, do you
13 know who it was turned over to?
14 A. Tiffany -- I don't see her name
15 here. I do not remember her last name.
16 Q. And was she in a different
17 group?
18 A. She was.
19 Q. What group was she in?
20 A. I believe chargebacks.
21 Q. So if you turn to the next
22 page, page 4, it says, "DEA policy on
23 suspicious orders."
24 A. Okay.
25 Q. And one of the bullet points

Page 135

1 is, "Registrant is reminded that the
2 responsibility does not end merely with the
3 filing of suspicious order report."
4 A. Correct.
5 Q. What does that mean to you?
6 A. That's referring to the report
7 that we were sending on a monthly basis.
8 Q. And so what are your additional
9 responsibilities other than filing -- well,
10 strike that.
11 What are the responsibilities
12 you have after filing your suspicious order
13 report?
14 A. Well, not only after filing it,
15 but during the interim, remember this was a
16 month-to-month report that we filed and it
17 was at the end of the month. So during a
18 month our -- our responsibilities were to
19 continue to look at the orders independent of
20 a report to see if there was unusual order
21 activity or -- or unusual orders being placed
22 that were out of the norm for that particular
23 customer.
24 As I talked about earlier this
25 morning, on the bulk side, our CSRs had a

Page 136

1 good feel who our customers were. We dealt
2 with them for years. And there wasn't that
3 many distributors in that that were -- or
4 drug manufacturers at that time. So we had a
5 pretty good idea of what their order patterns
6 were and that.
7 And so if we felt something was
8 unusual or whatever, we would bring that up
9 to the business manager for the product
10 and/or the salesperson.
11 Q. And when did you become -- when
12 did you -- when were you placed in charge of
13 the dosage products?
14 A. 2008.
15 Q. 2008.
16 So --
17 A. Fall of 2008, I believe.
18 Q. So would have been after this
19 presentation, but --
20 A. Yes.
21 Q. A couple months after?
22 A. Yes.
23 Q. And so with respect to this
24 bullet point and your responsibilities on the
25 dosage side of Mallinckrodt's business, what

Page 137

1 additional responsibilities did you have
2 other than filing the suspicious order
3 report?
4 A. On the bulk side?
5 Q. No, on the dosage side.
6 A. Oh, at that time I did not have
7 any responsibilities. I'm sorry.
8 Q. Well, this -- you've got a
9 bullet point here that says, "Registrant is
10 reminded that their responsibility does not
11 end merely with the filing of suspicious
12 order report."
13 A. This is Cathy -- this would be
14 Cathy Stewart's responsibility.
15 Q. Understood.
16 But this requirement would also
17 have applied to you when you took over the
18 dosage side of the business, correct?
19 A. After our -- after our new
20 reporting system was put in place.
21 Q. So what additional
22 responsibilities -- after the new reporting
23 system gets put in place --
24 A. Okay.
25 Q. -- what additional

Page 138

1 responsibilities did you have other than
 2 filing the suspicious order report?
 3 A. We no longer file that report.
 4 Our new monitoring system took the place of
 5 that. The DEA didn't -- no longer wanted us
 6 to send that report.
 7 So during the time period of
 8 2000 -- late 2008 and 2009, we worked on
 9 our -- and this is discussed in this
 10 presentation -- this team that was put
 11 together worked on coming up with a new
 12 report.
 13 My responsibilities after it
 14 was put in place was to receive the daily
 15 reports, peculiar order reports, that flagged
 16 the orders that were out of the log
 17 rhythms {sic} of the normal order patterning.
 18 Okay.
 19 And my job, which I think I
 20 kind of discussed earlier, was to -- the
 21 orders that were flagged was to then talk to
 22 the CSRs, the business managers, and the
 23 sales force that were involved with this
 24 particular customer that we were selling to
 25 and trying to explain why the order pattern

Page 139

1 was not being followed or why this was an
 2 unusual or peculiar order.
 3 Q. And so -- well, so when did
 4 this enhanced SOM policy become effective?
 5 A. I believe it was in the fall
 6 of 2009 is when we put it in place. This was
 7 after -- after months of working on what we
 8 wanted to see in the report. This is after
 9 we tested -- put it in a test mode and ran it
 10 parallel with our order entry system to see
 11 if there was anything kicking out that
 12 shouldn't been, and then we put it in what I
 13 call live production.
 14 Q. And so prior to 2009, what
 15 policy and procedures were in place regarding
 16 dosage products?
 17 A. So just our normal due
 18 diligence of the DEA requirements of making
 19 sure that we had the 222 forms prior to the
 20 order being shipped. All orders were placed
 21 on hold prior to that form being received.
 22 So that was our policy.
 23 Q. And you -- did you have any
 24 policy or process in place to identify
 25 suspicious dosage orders between the fall

Page 140

1 of 2008 and the fall of 2009?
 2 A. As I discussed, just our normal
 3 DEA compliance with the 222 forms and that.
 4 We were working on the process.
 5 Other than the CSRs bringing up
 6 a suspicious order based upon their
 7 knowledge, we did not have a -- a suspicious
 8 order program in place at that time as we
 9 developed it.
 10 Q. So in -- let's say we're
 11 talking January of 2009 here.
 12 A. Okay.
 13 Q. A manufacturer -- I'm sorry, a
 14 distributor for the dosage products submits
 15 an order that is, say, more than two times
 16 what it requested the prior month, that would
 17 not have been flagged for further review or
 18 investigation?
 19 A. If the CSR noticed that it was
 20 a larger order than normal based upon past
 21 history, which we had on our computer, they
 22 would bring it to the attention of -- of the
 23 salesperson or the business manager for
 24 approval to ship it.
 25 Q. And was there a threshold that

Page 141

1 was being applied, or how was the CSR to know
 2 that this was an unusual, large order?
 3 A. Just from past order history
 4 that was on the sales -- on the computer.
 5 Q. And so any order that was
 6 larger than the past sales history, or did it
 7 have to be larger by a certain amount?
 8 A. There wasn't a formal program
 9 in process. As this -- as this suspicious
 10 order thing points out, we were in the
 11 process of coming up with a new program, so
 12 from that standpoint, we didn't have a -- a
 13 computer system that was doing it. It was
 14 just informal.
 15 Q. So I just want to make sure I
 16 understand the chronology here.
 17 So prior to 2008, for the
 18 dosage products, what was the formula that
 19 was applied to determine if there were -- if
 20 an order was suspicious or not?
 21 A. Prior to 2008, to my -- best of
 22 my knowledge, because I was in the bulk area,
 23 they were reporting the best -- or the same
 24 way that I was, which was a monthly report.
 25 Q. And that is they would look at

Page 142

1 the current month's report -- I'm sorry, they
2 would look at the current order and compare
3 it to the prior month?
4 A. Rolling 12 months.
5 Q. On a rolling 12-month basis.
6 And what was the threshold that
7 would trigger it being viewed as suspicious?
8 A. The average of that 12-month.
9 Two times that.
10 Q. Two times that.
11 Okay. So prior to 2008, on the
12 dosage -- sorry.
13 A. Let me -- let me qualify that.
14 I was not over that program at
15 the time. I was not in dosage, but I believe
16 that's what they were using, but I can't say
17 for sure. That question should be asked of
18 Cathy Stewart.
19 Q. Understood.
20 But to the best of your
21 knowledge, prior to 2008, the formula that
22 was in place regarding dosage products was
23 that you looked at the current order and
24 compared it to the 12-month rolling average,
25 and if that order was more than two times the

Page 143

1 12-month rolling average, that would be
2 flagged as a peculiar order?
3 A. I'm assuming that's what they
4 were doing.
5 Q. Okay.
6 A. That's what we did on the bulk
7 side.
8 Q. And then in 2000 -- late 2008,
9 when you assumed control of the dosage
10 products --
11 A. Uh-huh. After the -- after the
12 program was -- the new --
13 Q. After the program was --
14 A. Was put in place.
15 Q. -- was put in place, but before
16 the new formula was developed, you didn't
17 have a formula in place at all?
18 A. Correct.
19 Q. So you just got rid of the --
20 you no longer looked at the comparison
21 between the current order and the 12-month
22 rolling -- the two month -- I'm sorry?
23 A. The DEA asked us to discontinue
24 sending them that letter.
25 Q. Well, I understand that the DEA

Page 144

1 had asked -- had asked you to discontinue
2 sending them the report.
3 But did they also tell you that
4 you didn't need to look at that data anymore?
5 A. I don't remember.
6 Q. But nevertheless, that -- that
7 formula was discontinued, and until fall
8 of 2009, nothing replaced it; is that
9 correct?
10 MR. TSAI: Object to the form.
11 THE WITNESS: That's correct.
12 QUESTIONS BY MR. KAWAMOTO:
13 Q. So between the fall of 2008 and
14 the fall of 2009, your regulatory system
15 was -- well, strike that.
16 Between the fall of 2008 and
17 the fall of 2009, the only regulatory -- the
18 only regulatory requirement that you had in
19 place to guard against diversion for dosage
20 products was the 222 forms?
21 MR. TSAI: Object to the form.
22 THE WITNESS: You say -- when
23 you say "only," it was the -- part of
24 the DEA requirement program that we
25 have 222 forms and quota forms

Page 145

1 required that, and to make -- to say
2 "only" kind of, I think, minimizes
3 or -- is playing it down that it was
4 not an important part of the DEA
5 regulations. We still had that
6 requirement.
7 And keep in mind, we were -- we
8 were shipping to distributors who also
9 had requirements on having programs in
10 place. We were not shipping to the --
11 the end users. There was many layers
12 of other players in this -- in this --
13 I shouldn't say players, but other
14 people or companies that were involved
15 in the suspicious order process
16 besides Mallinckrodt.
17 So to say, yes, we did not have
18 a program in place at the time. The
19 DEA was well aware that we did not
20 have a suspicious order program in
21 place. They asked us to put one in
22 place, and we kept them informed --
23 and when I say "we," Karen Harper,
24 kept them informed -- on the progress
25 of developing the new program, and to

Page 146

1 my knowledge, they were fine with
2 that.
3 QUESTIONS BY MR. KAWAMOTO:
4 Q. But nevertheless, if you were
5 to compare January of 2008 with January
6 of 2009, the regulatory requirements in
7 effect on January of 2009 would be less than
8 the regulatory effects in January of -- than
9 the regulatory requirements for January
10 of 2008, that's correct?
11 MR. TSAI: Object to the form.
12 THE WITNESS: I would have to
13 agree, yes.
14 QUESTIONS BY MR. KAWAMOTO:
15 Q. Okay. Why was it important to
16 have -- strike that.
17 With respect to the
18 pre-enhanced SOM program, you know -- well,
19 strike that.
20 Why did Mallinckrodt have this
21 12-month rolling -- this two times the
22 12-month rolling average standard in place?
23 What was its purpose?
24 A. The DEA asked us to report on a
25 monthly basis to them suspicious orders, what

Page 147

1 they called suspicious order, to develop a --
2 a program, which I described to you, and to
3 send that to them on a monthly basis.
4 Q. And this was in addition to the
5 222 form requirement, correct?
6 A. The quota form, yes.
7 Q. Yes.
8 So why -- what was the benefit
9 of this added regulatory requirement given
10 that you had the quota form in place?
11 A. I can't answer that. That's
12 a -- that's a question that you would have to
13 ask the DEA or Karen Harper.
14 Q. But you would agree that this
15 was --
16 A. This was what was asked of us.
17 We came up with a formula, and I think you
18 can even see the -- that we submitted to them
19 and they approved as far as the monthly
20 reporting basis, and that's what we went
21 with.
22 MR. KAWAMOTO: Well, so it's
23 12:30 now, Rocky. Do you want to take
24 a break for lunch?
25 MR. TSAI: That's okay.

Page 148

1 MR. KAWAMOTO: Do you want to
2 come back at 1:15, 1:30?
3 MR. TSAI: Let's do 45 minutes.
4 Is that okay?
5 THE WITNESS: Good.
6 VIDEOGRAPHER: We're going off
7 the record at 12:28 p.m.
8 (Off the record at 12:28 p.m.)
9 VIDEOGRAPHER: We're back on
10 the record at 1:19 p.m.
11 QUESTIONS BY MR. KAWAMOTO:
12 Q. So, Mr. Rausch, in terms of the
13 bulk product side of the business, in 2007,
14 were you aware that Purdue pleaded guilty
15 with respect to its opioid business in
16 federal court?
17 A. No, I'm not.
18 Q. So were you aware that the
19 government was conducting an investigation
20 into Purdue?
21 A. I don't remember that.
22 Q. Okay. And you don't have any
23 knowledge or awareness or any recollection of
24 the fact that, for example, the Purdue
25 general counsel entered a guilty plea in

Page 149

1 connection with that investigation?
2 A. I don't have recollection of
3 that, no.
4 Q. Now, in terms of screening your
5 customers on the bulk side of the business,
6 is that information that you would take --
7 you would have wanted to take into account in
8 determining whether or not to ship your
9 products to them?
10 MR. TSAI: Object to the form.
11 THE WITNESS: I would say, yes,
12 probably, it would be. Yes.
13 QUESTIONS BY MR. KAWAMOTO:
14 Q. Okay.
15 A. If they were -- if they were --
16 was their license suspended; do you know?
17 Q. I don't believe there was a
18 license suspension. I think it was a -- it
19 was a criminal indictment relating to
20 their -- to aspects of their business.
21 A. Okay. Oh.
22 And what was your question,
23 again?
24 Q. Well, is this information -- in
25 terms of screening your customers -- well,

Page 150

1 strike that.
2 You would agree that it is
3 important for Mallinckrodt to screen its
4 customers?
5 A. I agree.
6 Q. And part of that screening
7 should involve taking into account, you know,
8 whether they have any regulatory violations,
9 whether there are any pending investigations,
10 by the DOJ, the DOA or a state Attorney
11 General; is that fair?
12 A. We would continue to monitor
13 the orders that were being placed by them,
14 and if Karen Harper informed us that we were
15 not supposed to ship it to them anymore, even
16 though you mentioned that they did not have
17 their license suspended or whatever, I think
18 unless we were informed otherwise, we
19 probably would continue our order processing,
20 monitoring as it was then.
21 Q. So was the -- was the license
22 suspension the only reason Mallinckrodt would
23 stop shipping products to a customer?
24 A. I'm trying to think if there's
25 other reasons that I can think of offhand.

Page 151

1 If Karen wanted us to stop for
2 whatever reason, other than license
3 suspension, she would inform us to do so, and
4 I don't remember if she did or not.
5 Q. And do you have any -- do you
6 recall -- strike that.
7 Do you have any recollection of
8 Karen asking you to stop shipment for someone
9 for a reason other than a license suspension?
10 A. I don't recall.
11 (Mallinckrodt-Rausch Exhibit 6
12 marked for identification.)
13 QUESTIONS BY MR. KAWAMOTO:
14 Q. So I would like to mark this as
15 Exhibit 6.
16 And it is -- it bears the Bates
17 number MNK-T1_419993. It's Exhibit 6.
18 So, Mr. Rausch, have you seen
19 this document before?
20 A. I don't remember it.
21 Q. Okay.
22 A. That doesn't mean I didn't see
23 it, but I don't remember it.
24 Q. And this is a DEA compliance
25 procedure, controlled substance suspicious

Page 152

1 order monitoring, and it says, "Revision
2 number draft 3, published 6/02/2008."
3 A. Okay.
4 Q. So would this document have
5 been prepared in connection with the
6 suspicious order monitoring team and your
7 enhanced SOM?
8 A. Yes, it seems to be in the same
9 time period that we were working on it.
10 Q. Okay. And do you know if this
11 document was ever finalized?
12 A. I don't remember.
13 Q. Was there a written document
14 that memorialized Mallinckrodt's enhanced
15 suspicious order monitoring program?
16 A. I don't remember.
17 Q. So if I were to -- let's say in
18 2014, if I were to be hired by Mallinckrodt
19 to oversee its enhanced suspicious order
20 monitoring program with respect to dosage
21 products and I were to ask to see what the
22 policy was, what would you -- what would you
23 give to me?
24 MR. TSAI: Object to the form.
25 THE WITNESS: In 2014?

Page 153

1 QUESTIONS BY MR. KAWAMOTO:
2 Q. Yes.
3 A. I didn't work for the company
4 in 2014.
5 Q. Well, fair enough.
6 In 2013, if I'm coming in as
7 your replacement --
8 A. Right.
9 Q. -- to oversee the dosage
10 products, and I ask -- and my responsibility
11 is to oversee --
12 A. Right.
13 Q. -- the enhanced suspicious
14 order monitoring program, what document would
15 you have provided to me?
16 A. Most likely it would have a
17 document like this, because we did have -- we
18 did have documents for how things work at
19 customer service, and I am sure we had
20 something -- I would guess that we did have
21 something in place similar to this on what
22 customer service would do as far as the
23 procedure.
24 Q. Okay. So turning to page 2 of
25 this -- of this draft policy?

Page 154

1 A. Okay.
2 Q. Do you see the section entitled
3 "Credit Department"?
4 A. I do.
5 Q. And it says, "Performs Dun &
6 Bradstreet and/or other information checks on
7 new controlled substance customers to
8 determine credit worthiness."
9 Was this part of the enhanced
10 SOM program for dosage products?
11 A. I'm not -- I'm not sure if it's
12 part of the enhanced. I'm not sure what the
13 credit department did prior to this period of
14 time, but I know they did -- they did check
15 Dun & Bradstreet to -- prior to the new
16 program.
17 I would say the -- the part
18 about referring the new customer account to
19 the director of DEA compliance would be new,
20 and the conducts periodic checks for existing
21 accounts would also be new.
22 Q. And I guess in terms of sort of
23 overall what I'm trying to accomplish, I'm
24 trying to understand whether or not these
25 components made it into the final version of

Page 155

1 the enhanced SOM program.
2 So with respect to the enhanced
3 SOM program or the final version, would the
4 credit department have performed a Dun &
5 Bradstreet --
6 A. Yes.
7 Q. -- check?
8 A. Yes.
9 Q. Okay.
10 A. I didn't work in that
11 department, but I'm sure that that was part
12 of their -- their process going forward.
13 Q. And what was the purpose of
14 performing that review or asking Dun &
15 Bradstreet to perform that review?
16 A. It would just give them a
17 history of -- credit history of sales and
18 that type of thing, if they had, you know,
19 any debt or had gone bankrupt or that type of
20 thing. I'm not speaking as a credit person,
21 but I think that's what that was part of it.
22 Q. So this would have addressed
23 the concern -- I mean, the concern that
24 Mallinckrodt had about the financial solvency
25 of the institution --

Page 156

1 A. Correct.
2 Q. -- and presumably whether it
3 would be able to pay any debts it owed to
4 Mallinckrodt, correct?
5 A. Correct.
6 Q. Would this have helped prevent
7 diversion in any way?
8 A. No, I think this is -- this is
9 just a -- part of the credit department's
10 ongoing procedure.
11 Like I said, it was probably
12 two and three of this credit department that
13 you have here that would be new to the
14 compliance, SOM, suspicious order.
15 Q. When you say "two or three,"
16 what do you mean?
17 A. Sentences two or three under
18 the credit department.
19 Q. Okay. So just so I'm clear,
20 Dun & Bradstreet was not related to diversion
21 control?
22 A. No, that was always a -- a
23 check that they did prior to -- to putting in
24 a new customer.
25 Q. Okay. And so Section 2 is --

Page 157

1 refers to the new account customer DEA
2 compliance of the new account has no
3 historical or financial information available
4 or if the data shows liens, lawsuits or other
5 information which might raise suspicions to
6 the legitimacy of the new account company.
7 And how does that help
8 prevent -- or how does that assist in
9 diversion control?
10 A. Well, again, you're speaking
11 about an area that I was not part of, okay,
12 so I can't answer that question. That's a
13 credit department question.
14 Q. And so the credit -- well, you
15 indicated that part of your responsibilities
16 was you identified -- part of your
17 responsibilities under the enhanced SOM
18 program is that you would identify peculiar
19 orders or they would be identified to you on
20 a report; is that fair?
21 A. That's correct.
22 Q. And then you would then take
23 that order and interact with various people
24 in the sales department to determine if there
25 was a basis for that order; is that correct?

Page 158

1 A. Correct.

2 Q. Did you ever interact with the

3 credit department to determine if there was a

4 basis for the order?

5 A. This is referring to new

6 customer accounts, okay. So the order would

7 never -- there would never be an order placed

8 unless the credit department established them

9 as a -- as a new customer. Okay. So that

10 would be preliminary work to me ever

11 receiving an order.

12 Q. And was there any effort made

13 to update this information?

14 A. There was a yearly -- there was

15 a yearly form that was sent out by the credit

16 department from what I can remember, that

17 they had to -- it was a checklist that they

18 had to fill out and send back to the credit

19 department to keep their account current, and

20 it had questions concerning the compliance

21 that we were doing for the suspicious order

22 monitoring program.

23 This wasn't something new that

24 was developed. I can't speak to what was all

25 involved, but there was a yearly report or

Page 159

1 checklist that was sent out to the customer

2 and they had to fill it out and send it back

3 to them to keep them current as the customer.

4 Q. Okay. And this was -- this was

5 all being -- this was being done in

6 connection with --

7 A. Our enhanced reporting system

8 and suspicious order reporting.

9 Q. Okay. But credit didn't have

10 any role in reviewing individual orders?

11 A. No.

12 Q. Okay. Now, the next section is

13 on field sales.

14 And by "field sales," I assume

15 we're referring to the -- the salespeople in

16 the field?

17 A. Correct.

18 Q. Okay. It says, "Completes site

19 survey checklist for new controlled substance

20 customers," and then "conducts an on-site

21 visit, including taking photographs inside

22 and out for review by security director and

23 DEA compliance manager."

24 A. Uh-huh.

25 Q. Do you know what the purpose of

Page 160

1 the on-site visit and the photographs were?

2 A. The reason for that is take a

3 look at the physical property itself to see

4 if it looked like a legitimate business.

5 They didn't want it to be running out of

6 somebody's house or whatever, so it had to be

7 like, you know, physically have to look like

8 there's a company that you would want to sell

9 to and not being run out of back -- back of a

10 hotel or something like that.

11 So this information was passed

12 on to the DEA director, I believe, is --

13 yeah, it's security.

14 Q. And your -- this requirement

15 applies to Mallinckrodt's customers, correct?

16 A. Yes.

17 Q. Would it be your expectation

18 that the distributors would be doing

19 something similar for their customers?

20 A. I -- I can't answer that.

21 Q. From a standpoint of diversion

22 control, do you think it would be important

23 for a distributor to do this?

24 MS. YOCUM: Objection. Form.

25 THE WITNESS: I can't speculate

Page 161

1 on what they -- what we -- they would

2 feel is important.

3 Everybody had their own

4 program, okay. We didn't have any

5 guidelines from the DEA on what our

6 program should look like.

7 So as far as what the other

8 companies or distributors did as far

9 as their program, I don't -- I can't

10 answer that.

11 QUESTIONS BY MR. KAWAMOTO:

12 Q. Well, I understand that you --

13 sorry.

14 A. Well, to answer that, you're

15 asking me would I feel that that would be

16 something that they would want to do?

17 Q. Yes.

18 A. I would say yes.

19 Q. Now, for the customer service

20 representatives, they break this up into bulk

21 narcotics and dosage customer service reps.

22 Do you see that?

23 A. I do.

24 Q. And so you would have been

25 responsible for the dosage customer service

Page 162

1 representative section; is that fair?
2 A. At that time, I was -- fall
3 of 2008.
4 Q. Okay.
5 A. So kind of in a transit year,
6 but eventually, yes, I become manager --
7 manager over the dosage area.
8 Q. Okay. And on the top of --
9 well, at the bottom of page 2 of 5 and going
10 on to page 3 of 5, do you see, "Dosage
11 customer service representatives will perform
12 the following activities"?
13 A. I'm sorry, which one am I
14 supposed to be looking at?
15 Q. At the bottom of page 2 of 5.
16 So at the bottom of 41994. Under "Dosage
17 Customer Service Representatives."
18 A. Okay. Page 3?
19 Q. Yes.
20 A. Okay.
21 Q. No, I'm sorry, page 2 of 5.
22 A. Okay. Under the "bulk"
23 section?
24 Q. Under the "dosage." So beneath
25 "bulk."

Page 163

1 A. Okay. This is page 2.
2 Q. Uh-huh.
3 A. And this is page 3.
4 Q. So page 2 would be this section
5 right here.
6 A. Oh, okay. Under --
7 Q. So it says, "Dosage customer
8 service representatives."
9 A. Okay. Okay.
10 Q. Okay. And it has -- it lists
11 various requirements that start on page 2 and
12 follow on to page 3.
13 Do you see that?
14 A. I do.
15 I didn't -- I haven't read it
16 yet, though.
17 Q. Okay.
18 A. Do you want me to read it?
19 Q. Yes, please.
20 A. Okay.
21 This looks like a working
22 document from what I can see, because I can
23 see there's some -- there's some questions
24 here where it says, "Dosage customer service
25 will perform the following activities," and

Page 164

1 it says, "Need clarification."
2 And again, this -- it does say
3 draft, so this is a working document that was
4 not the final document.
5 Q. And so -- and that's part of
6 why I'm asking these questions. I want to
7 see if these -- if these responsibilities
8 were transferred or were put into the final
9 policy.
10 A. Okay.
11 Q. But the first one is, "Verify
12 that the customer has a valid DEA
13 registration certificate."
14 I assume that was part of the
15 final policy?
16 A. Yes.
17 Q. Okay. Then it also says,
18 "Ensure that the customer has provided a
19 properly executed DEA 222 form for C-I and
20 C-II substances."
21 A. Correct.
22 Q. Was that part of the final
23 policy?
24 A. Yes.
25 Q. Okay.

Page 165

1 A. That was part of our policy
2 before the -- this program, but, yes, go
3 ahead.
4 Q. And then it also says, "Flag
5 orders that deviate from the norms in terms
6 of quantity order, frequency of order and/or
7 pattern of normal order placement. CSRs will
8 evaluate the circumstances of the order.
9 This evaluation should be based on their
10 knowledge of the specific customer and the
11 industry in which the customer operates, and
12 should the circumstances deviate from the
13 norm, upon completion of the order, place
14 same on hold and notify security and customer
15 service manager."
16 A. Okay.
17 Q. Do you see that?
18 A. Yes.
19 Q. Was that part of the final
20 policy?
21 A. That was part of our ongoing
22 policy. Okay.
23 So as I talked while we were --
24 before where we were discussing what was --
25 what took place, why we're developing our

Page 166

1 final policy, this is the type of thing --
2 type of thing I was talking about where the
3 CSR was, you know, knew the customer best and
4 was to keep us informed if they saw something
5 that was being ordered that was different
6 from normal.
7 Q. And how was the CSR to
8 determine whether something was different
9 from normal?
10 A. Just from their knowledge of
11 the customer, like I discussed earlier. Now,
12 if they --
13 Q. I'm sorry. Go ahead.
14 A. Yeah, because this is referring
15 not -- this is -- okay. This is -- we're
16 looking at bulk here. Dosage is over here.
17 Yeah, "This evaluation should
18 be based on their knowledge of the specific
19 customer and the industry in which the
20 customer operates, and should the
21 circumstances deviate from the norm, upon
22 completion of the order, place same on hold
23 and notify security," which would be Karen
24 Harper's group, "and customer service
25 manager."

Page 167

1 Q. And so was this --
2 A. That was in place while we were
3 developing our program, and also as -- as we
4 went on, our program would kick out these
5 orders, so the CSRs still had the chance, as
6 they were placing the order, to say, "Hey,
7 something's wrong here," and bring it to the
8 attention of the customer service manager or
9 the DEA compliance officer, but we also had
10 our program in place that would flag orders
11 that were considered peculiar.
12 Q. And that program in place to
13 flag orders, that was what was activated in
14 the fall of 2009?
15 A. That's correct.
16 Q. So with respect to the ability
17 of the CSR to identify orders that they think
18 are peculiar, were there standards they were
19 supposed to apply in that respect?
20 A. Just -- just orders that
21 were -- seemed out of place to them.
22 Q. Okay.
23 A. As far as I remember.
24 Q. And how many different CSRs did
25 you have?

Page 168

1 A. I think there were five.
2 Q. So you have five CSRs.
3 A. Right.
4 And they were -- they were
5 responsible for particular customers.
6 Q. Okay. And the CSRs were part
7 of the sales team, were they not?
8 A. No. They reported into
9 logistics.
10 Q. Yeah.
11 And so how were the CSRs
12 compensated?
13 A. They weren't under the bonus
14 program. They just had a salary.
15 Q. So they didn't have a bonus
16 program; it was just a salary?
17 A. Yes.
18 Q. Okay. And in terms of the
19 factors that a CSR was to consider in
20 determining whether an order was peculiar,
21 was there a list of factors?
22 A. I'm sorry, say that again.
23 Q. Let me rephrase that question.
24 So as I understand it, the CSR
25 had the ability to flag an order that he or

Page 169

1 she believed was peculiar or unusual; is that
2 fair?
3 A. For that customer, yes.
4 Q. Okay. And in terms of
5 assessing whether an order was peculiar or
6 unusual, was there a set of -- was there a
7 written standard that they were supposed to
8 apply or a set of factors they were supposed
9 to look to?
10 A. Just past order history for
11 that customer, and then they would talk to --
12 bring it to my attention or to the business
13 manager and ask them if they knew why this
14 particular order was different from what
15 their normal order pattern was, and then
16 if -- go ahead.
17 Q. And in terms of past order
18 history, what we're talking about is just
19 looking at whatever -- whatever they had --
20 whatever they had ordered previously?
21 A. Correct.
22 Q. And was there any threshold
23 that was applied in terms of, you know, an
24 order X percentage above the prior history
25 would be viewed as peculiar, or was it really

Page 170

1 left up to the CSR?
2 A. I don't remember, to be honest
3 with you, what -- what we gave them as
4 parameters, whether it was an X factor or if
5 it's just based upon their -- their knowledge
6 and the order history during this time period
7 while we were developing our suspicious order
8 program.
9 Q. And did you have any program in
10 place to audit the CSRs to make sure that
11 they were -- they were accurately picking up
12 on suspicious orders?
13 A. Not that I remember.
14 Q. Were CSRs evaluated on their
15 ability to properly identify suspicious
16 orders?
17 A. Were they evaluated?
18 Q. Well, let me -- let me rephrase
19 that question.
20 The CSRs were subject to an
21 annual review process, correct?
22 A. That's correct.
23 Q. Was part of this annual review
24 process a review of, you know, whether they
25 accurately identified suspicious orders?

Page 171

1 MR. TSAI: Object to the form.
2 THE WITNESS: Not that I
3 remember.
4 QUESTIONS BY MR. KAWAMOTO:
5 Q. So do you have any way of
6 ascertaining whether or not the CSRs
7 successfully identified suspicious orders?
8 A. Well, I just -- I just want to
9 point out not only were our customer service
10 reps and Mallinckrodt responsible for
11 identifying suspicious orders, but also the
12 people that we sold to, which were the
13 distributors, and the distributors to the
14 pharmacies all were responsible for doing
15 this.
16 So as far as diversion and that
17 type of thing, there was -- there was a long
18 list of people in between us and the customer
19 or the end user.
20 Q. Mallinckrodt had a number of
21 different distributors that it did business
22 with, correct?
23 A. That's correct.
24 Q. Do you know if any of these
25 distributors ever had their licenses revoked

Page 172

1 by the DEA?
2 A. If they did -- and I don't want
3 to say I remember that any particular one
4 was, but I believe that there was, but I
5 couldn't tell you who it was, and if it was
6 the DEA would notify us and then we would no
7 longer sell to them. But I can't say yes or
8 no for sure that there was a -- a distributor
9 who was -- had their license suspended.
10 Q. Well, based on your -- your
11 reading or your viewing of news reports, are
12 you aware of distributors that appear to have
13 been abusing the system?
14 A. In 2008?
15 Q. Well, in 2008 up till 2017.
16 A. I think there was, yes.
17 Q. Okay. And, you know, is it
18 fair to say that these distributors were not
19 properly applying whatever standards they
20 were supposed to prevent diversion?
21 MS. YOCUM: Objection. Form.
22 QUESTIONS BY MR. KAWAMOTO:
23 Q. So you can answer.
24 A. Oh, okay.
25 That's -- that's speculation on

Page 173

1 my point. I don't know.
2 Q. Was it consistent with your
3 understanding of Mallinckrodt's
4 responsibilities with respect to the DEA
5 rules and regulations that Mallinckrodt could
6 rely on the distributors to do their job to
7 stop diversion, or were you independently
8 responsible for preventing suspicious orders?
9 A. I believe that we were
10 responsible for monitoring our customers and
11 that's what we were working on at the time.
12 Q. And so if your customers were
13 improperly distributing Mallinckrodt
14 products, then these Mallinckrodt products
15 would contribute to the diversion crisis,
16 wouldn't they?
17 MR. TSAI: Object to the form.
18 MS. YOCUM: Object to the form.
19 THE WITNESS: That's possible.
20 QUESTIONS BY MR. KAWAMOTO:
21 Q. Well, it's more than possible;
22 it's likely, sir, isn't it?
23 MR. TSAI: Object to the form.
24 THE WITNESS: If you say so.
25

Page 174

1 QUESTIONS BY MR. KAWAMOTO:
2 Q. So going back to this document,
3 I think it's Exhibit 6 --
4 A. Exhibit 6?
5 Q. Yes.
6 We were looking at page --
7 A. Okay.
8 Q. -- 3 of 5.
9 A. Uh-huh.
10 Q. In terms of -- there's a
11 paragraph here that says, "If the dosage
12 customer service representatives are
13 contacted by a new customer asking that a
14 account be set up and the interview process
15 yields questionable results, the CSR will
16 obtain the following information from the
17 customer and forward that information in an
18 e-mail to the director of security as well as
19 the customer service manager."
20 Do you see that?
21 A. I do.
22 Q. And was that part of the
23 enhanced SOM program?
24 A. I believe so.
25 Q. And do you recall this ever

Page 175

1 occurring?
2 A. Again, if -- this was a working
3 document, and if -- this probably would have
4 went to the director of security, and if he
5 felt that we should not set them up, we
6 probably would not.
7 Q. Okay. But do you recall any
8 instances where the director of security
9 declined to set up an account because of
10 concerns about the interview process?
11 A. No. I don't recall that.
12 Q. And this -- this -- this
13 paragraph references both the director of the
14 security as well as the customer service
15 manager.
16 A. Right.
17 Q. Do you see that?
18 A. Uh-huh.
19 Q. And that would have been you
20 for dosage products in the 2008 to 2013 time
21 period?
22 A. Going forward, it would have
23 been me.
24 Q. Okay. Do you recall ever
25 receiving reports from the customers -- from

Page 176

1 customer service representatives about
2 questionable customers?
3 A. I don't remember.
4 Q. And so during the five years
5 that you were the customer service manager
6 for dosage products, you don't recall ever
7 receiving a customer service report
8 recommending that an account not be set up;
9 is that fair?
10 A. I don't remember, yes.
11 I don't know if that was part
12 of the final -- how a draft the final -- this
13 is the draft. I don't know if that was the
14 final product or not.
15 Q. Okay. So going down to the
16 next section, which is "Customer Service
17 Manager."
18 A. Uh-huh.
19 Q. It says -- well, actually, can
20 you review that section?
21 A. Okay.
22 Q. So it references a peculiar
23 order daily report.
24 Was this part of the enhanced
25 SOM program?

Page 177

1 A. It was proposed. I don't think
2 it ever went into effect.
3 Q. Okay. So did you -- did you
4 ultimately receive a report of suspicious
5 orders?
6 A. Yes. In August when we
7 finalized --
8 Q. Finalized the program?
9 A. -- the program, yes.
10 Q. In what way was that report
11 different than the peculiar order daily
12 report that's described here?
13 A. There was more information that
14 was used for determining whether an order was
15 peculiar than what is outlined here.
16 Q. Okay. And what was the
17 additional information that was used?
18 A. Yeah, like I mentioned before,
19 it's got unusual large, unusual frequency and
20 our deviation quantity to establish order
21 pattern.
22 From what I remember, it also
23 looked at that -- that family that I talked
24 about where if they ordered 50 pills, as you
25 described it, and now they ordered 100 pills,

Page 178

1 it would look -- would be looking at the
 2 total, not just that particular SKU. So that
 3 was added into it.
 4 And I believe there's some
 5 other factors that would -- that were put
 6 into the -- into the program other than it
 7 was just outlined here.
 8 Q. Okay. And going back to the
 9 family point that you had.
 10 A. Uh-huh.
 11 Q. Is this a difference between
 12 looking at orders on a SKU basis versus an
 13 API basis? Is that one way to think of this?
 14 A. Yeah. Yes.
 15 Q. And so what is an API?
 16 A. Well, API is an active
 17 pharmaceutical ingredient.
 18 Q. And what is --
 19 A. Essentially what that is is
 20 that API is the active ingredient in a -- in
 21 a -- let's use a tablet, for instance. To
 22 make a tablet, you can't just make it from
 23 the active ingredient. There's other
 24 chemicals that have to be added to it so it
 25 can be pressed into a tablet. Okay. That

Page 179

1 had no chemical or no -- how do I want to say
 2 it? It did nothing for the patient, okay,
 3 that had nothing to do with it. It was just
 4 how to format a pill or that. So that would
 5 be the inactive ingredients in a tablet.
 6 Does that make sense?
 7 Q. I believe I understand.
 8 I guess -- well, let me ask you
 9 this.
 10 A. So let me better explain it.
 11 Q. Okay.
 12 A. Okay. We made -- say we wanted
 13 to make hydrocodone, okay. That was the
 14 active ingredient in the tablet.
 15 To that, we would add compac,
 16 which is acetaminophen that was compressible.
 17 Okay. So those two would be added together,
 18 and they would be put in pill presses and
 19 make the product, the end product.
 20 But the inactive ingredient had
 21 no benefit to the -- or could -- did not have
 22 any drug ingredient in it.
 23 Q. And so what is the -- what is
 24 the diversion benefit of looking at the API
 25 as opposed to the SKU? Or let me rephrase

Page 180

1 that.
 2 What is the concern you have
 3 with respect to looking at a SKU that is
 4 fixed if you look at the API?
 5 That's what I'm trying to
 6 understand.
 7 A. Okay. So if you had 5 --
 8 5 milligrams in a tablet and -- one tablet
 9 and you had 10 milligrams in another tablet,
 10 you would want to look at the total for that
 11 particular -- the API of that particular
 12 product. Okay.
 13 So if a customer ordered
 14 10 milligrams of that family, say
 15 hydrocodone, and then decided, "Well, I
 16 ordered too many of those, I'm going to order
 17 5 milligrams of that active ingredient" -- to
 18 keep from the orders looking like they were
 19 heavy, they could order one and one, one and
 20 one, and it wouldn't trigger the two times or
 21 whatever of the suspicious order program.
 22 It's a way around the infrequent -- not
 23 infrequent, but, you know, twice the amount
 24 of a particular order.
 25 Follow me?

Page 181

1 Did I explain that well enough
 2 for you?
 3 Q. Well, I'm still trying to
 4 understand this. I guess let me -- let me
 5 ask it this way then.
 6 A. All right.
 7 Q. What is -- what is the problem
 8 by just looking at the prior order history on
 9 a SKU basis? What -- if you were to do that,
 10 what are you missing?
 11 A. On a SKU basis?
 12 Q. Yes.
 13 A. Okay.
 14 Q. How could you game the system
 15 if it was based on a SKU basis as opposed to
 16 the API basis?
 17 A. Okay. If I ordered, let's say,
 18 on a SKU basis, a hundred tablets of this one
 19 SKU, okay, then another SKU of the same
 20 product, okay, had a different number of
 21 tablets. Okay. If I ordered a hundred and
 22 then I went over to the other one and I
 23 ordered a hundred of that, okay, it would get
 24 under that -- that frequency of, say, if I
 25 ordered twice as many as normal of the

Page 182

1 hundred.
2 Q. Okay.
3 A. Or twice as many of the 50. So
4 if I split it up and ordered one and one,
5 okay, it wouldn't hit that threshold, okay.
6 They're ordering twice as many of the
7 hundreds as they normally do, if they bounce
8 back and forth.
9 Does that make sense?
10 Q. Okay. I think I understand.
11 And would it solve this problem
12 if you were to look at it on a SKU-by-SKU
13 basis or --
14 A. I don't understand your
15 question, to solve this problem.
16 Q. Actually, I'll withdraw that
17 question. I think I understand what you're
18 getting at.
19 Okay. And so other than
20 looking at essentially -- well, strike that.
21 So with respect to the peculiar
22 order report that you were receiving, in
23 addition to the information regarding size,
24 frequency and order pattern, it also took
25 into account the family of drugs, I guess, or

Page 183

1 they looked at things on an API basis.
2 A. Right.
3 Q. Were there other factors as
4 well?
5 A. There were, but I don't
6 remember all of them.
7 Q. Now, do you see the reference
8 to a do-not-ship list?
9 A. Yes.
10 Q. Was that part of the enhanced
11 SOM program?
12 A. Yes. What would -- well, it
13 was an ongoing -- I mean, Karen Harper would
14 get a report from the DEA of -- of customers
15 or other than customers that were potential
16 customers from the DEA that we were not to be
17 shipping to any -- it's kind of a warning
18 list, do not ship to these customers or
19 whatever.
20 And then what we would do is
21 flag -- if it was an existing customer, we
22 would flag that customer so that we could not
23 accept any orders into the system for that
24 customer.
25 Q. So this -- this do-not-ship

Page 184

1 list was entirely dependent on the DEA
2 saying, "Don't ship to this person"; is that
3 fair?
4 A. Yes.
5 Well, no. That we determine as
6 part of the program of suspicious activity.
7 So if we had found a customer
8 that was a suspicious order, we had said was
9 a suspicious order, and we could not verify
10 that it was a good order, then there was
11 flags in the system created that would flag
12 that customer that we could not accept one of
13 their -- their orders. That was part -- that
14 was part of the new program.
15 Q. And so --
16 A. Along with what the DEA sent
17 out.
18 Q. So just so I understand, there
19 are two ways to get on this list: One of
20 them would be the DEA would put them on the
21 list.
22 A. Right.
23 Q. The other way would be
24 Mallinckrodt would independently determine
25 based on the orders they're submitting that

Page 185

1 they -- that they are -- you know, their
2 orders are problematic or that there are
3 diversion concerns --
4 A. Yes.
5 Q. -- and put them on this list.
6 A. Yes.
7 Q. Okay. Who maintained this
8 list?
9 A. It was maintained in our order
10 entry system, and customer service -- or -- I
11 believe that customer service was in charge
12 of that, if it ever occurred.
13 Q. Okay. Do you recall how many
14 entities were put on this list in the 2008
15 through 2013 time period?
16 A. We did not have any suspicious
17 orders at that time, during that time period.
18 Q. So is it fair to say then that
19 no one was on this do-not-ship list?
20 A. Through the monitoring program.
21 Q. Okay. So the only entities
22 that were put on this list then were from
23 DEA?
24 A. At that time, yes.
25 Q. Then do you see at the very

<p style="text-align: right;">Page 186</p> <p>1 bottom of the page --</p> <p>2 A. Proposed preliminary dosage.</p> <p>3 Q. Yeah, proposed preliminary</p> <p>4 dosage formula, and then it follows on the</p> <p>5 following page as to what that formula is.</p> <p>6 A. And that's what I was trying to</p> <p>7 explain to you where it says add purchase</p> <p>8 quantities by product, all oxy products and</p> <p>9 again by individual SKUs. Okay. So it's</p> <p>10 looking at the -- the API also.</p> <p>11 Okay.</p> <p>12 Q. And so --</p> <p>13 A. It's pretty detailed.</p> <p>14 Q. So does this -- is this formula</p> <p>15 an accurate depiction of the formula that was</p> <p>16 applied to dosage products for the 2008</p> <p>17 through 2013 time period?</p> <p>18 A. Not 2008. I think this was</p> <p>19 in --</p> <p>20 Q. Sorry, my apologies.</p> <p>21 A. 2000 --</p> <p>22 Q. From fall of 2009 until 2013,</p> <p>23 is this the formula that was applied to</p> <p>24 dosage products?</p> <p>25 A. I believe that's -- again, this</p>	<p style="text-align: right;">Page 188</p> <p>1 taking the current order and comparing it to</p> <p>2 the rolling 12-month --</p> <p>3 A. Right.</p> <p>4 Q. I'll strike that.</p> <p>5 It was taking the current -- it</p> <p>6 was taking the current order and comparing it</p> <p>7 to the rolling 12-month average times two; is</p> <p>8 that accurate?</p> <p>9 A. Correct. Uh-huh.</p> <p>10 Q. And so this new formula was</p> <p>11 comparing the current order to a rolling</p> <p>12 12-month average times two, isn't that the</p> <p>13 factor for -- if there's a factor that</p> <p>14 says -- it says factor Schedule II controlled</p> <p>15 substances?</p> <p>16 A. Well, that -- that along with</p> <p>17 some other things that are also here.</p> <p>18 Customers will multiply -- with multiple</p> <p>19 ship-to locations should have their total</p> <p>20 aggregated at the sold-to level but also</p> <p>21 reviewed at the ship-to level. Okay.</p> <p>22 So it was not only looking at</p> <p>23 the individual -- it was looking at just not</p> <p>24 the individual distributors, but it was</p> <p>25 looking at the total that that distributor</p>
<p style="text-align: right;">Page 187</p> <p>1 was a work-in-progress draft, but I believe</p> <p>2 that this was part of that end product.</p> <p>3 Q. So looking at the end</p> <p>4 program --</p> <p>5 A. Uh-huh.</p> <p>6 Q. -- what was the formula applied</p> <p>7 to dosage products from fall of 2009</p> <p>8 through 2013? Can you tell me --</p> <p>9 A. What was the formula?</p> <p>10 Q. Yes, what was the formula.</p> <p>11 A. Well, it's written out here</p> <p>12 exactly what the formula consisted of.</p> <p>13 Q. So for --</p> <p>14 A. It's pretty complicated, so for</p> <p>15 me to verbally tell you, I don't know if I --</p> <p>16 if I could describe it well enough.</p> <p>17 Q. Well --</p> <p>18 A. It looked --</p> <p>19 Q. Sorry.</p> <p>20 A. It looked at order quantity --</p> <p>21 there was just a number of them that I don't</p> <p>22 remember all the formula. I couldn't spell</p> <p>23 it out -- spiel it out for you anymore.</p> <p>24 Q. Well, if we look at the</p> <p>25 pre-2007 formula, it was looking at -- it was</p>	<p style="text-align: right;">Page 189</p> <p>1 was purchasing.</p> <p>2 Had customer months for every</p> <p>3 record used in the above total month within</p> <p>4 the last -- customer center. Went down to</p> <p>5 zero.</p> <p>6 So okay. It's just writing --</p> <p>7 this is just writing out the formula of how</p> <p>8 it should be done.</p> <p>9 So you take that information,</p> <p>10 you divide the total quantity purchased by</p> <p>11 total customer months, then multiply -- okay,</p> <p>12 I'm sorry, what was your -- what were you</p> <p>13 going to say?</p> <p>14 Q. Well, looking -- I'm trying to</p> <p>15 understand the difference between the</p> <p>16 pre-2007 formula, which was for dosage</p> <p>17 products a rolling 12-month average times</p> <p>18 two --</p> <p>19 A. Okay.</p> <p>20 Q. -- and the formula under the</p> <p>21 enhanced SOM program.</p> <p>22 A. Okay. This is one part of the</p> <p>23 formula -- this is a formula right here of</p> <p>24 what it should look like. It also looked at</p> <p>25 your regular order patterns, okay. It looked</p>

Page 190

1 at, like I said, at the family, or the API,
 2 which we didn't look at pre-2009. The
 3 pre-2009 just looked at the order by double,
 4 okay.

5 So I think I've said three
 6 things already that the other -- that the
 7 original report that we sent to the DEA on a
 8 monthly basis did not have.

9 And I don't think this is the
 10 final version. It had even more.

11 Q. And in terms of how this
 12 formula was -- well, strike that.

13 How was this formula applied to
 14 Mallinckrodt orders?

15 A. Okay. So this was -- this was
 16 put in in our order entry system, and on a --
 17 on a daily basis all orders were compared to
 18 the log rhythms {sic} that we had set in
 19 place for our customers and orders.

20 If there was anything that did
 21 not fit the normal order pattern or what we
 22 would consider the normal order pattern based
 23 upon our guidelines and what we had put in
 24 place, it would flag that order and a report
 25 would print out that I looked at on a daily

Page 191

1 basis.

2 And it would show me the orders
 3 that had been flagged as peculiar. And as
 4 discussed earlier, I would take -- is that
 5 what you're looking for?

6 Q. Yes.

7 A. Okay.

8 Q. And how would it -- how
 9 would -- how would the program tell whether
 10 an order did not fit the normal order
 11 pattern?

12 A. Based upon these formulas that
 13 were put into the system.

14 Q. But what -- I mean, what
 15 specifically was this formula supposed to
 16 take into account? What specifically was the
 17 formula looking for in determining what a
 18 normal order pattern was and what a deviation
 19 from that was?

20 A. If it was -- if it didn't meet
 21 the criteria of the formulas that -- that we
 22 had put in place as far as -- for example,
 23 twice the orders in a rolling 12-month
 24 period, it would kick out. That's just one
 25 example. Okay.

Page 192

1 Another example is if it was,
 2 say, they hadn't ordered for two or three
 3 months and then all of a sudden we received a
 4 large order from a customer, that would be
 5 considered an irregular order pattern. Okay.
 6 That would kick out on this report.

7 Again, I -- I talk about the
 8 API. If their total API for an order was
 9 greater than whatever the criteria was for
 10 that, it would kick out.

11 Those were reasons for the
 12 order to kick out on the report.

13 Q. And where -- was this formula
 14 written down somewhere?

15 A. I believe what we put into the
 16 computer was probably written down somewhere.
 17 I don't remember exactly.

18 This was given to our
 19 information services people that were on the
 20 team and it was put into their systems, so it
 21 was probably -- it was documented by them.

22 Q. Okay. And did you work with
 23 anyone in particular in the information
 24 services team?

25 A. I believe it was on the --

Page 193

1 let's see.

2 I don't see any of the people
 3 listed from IS on this team that -- this
 4 report here, but there were -- I don't -- I
 5 don't remember the people's names that were
 6 from -- I remember Steve, but I don't
 7 remember his last name.

8 So they were -- they were part
 9 of the team and they were brought in when we
 10 came -- came to a point where we were ready
 11 to give them some -- give them information
 12 that we wanted implemented into the computer
 13 system, and we would have to write up a
 14 document spelling out exactly what it was
 15 that we wanted to be put into the system.

16 Q. And did you write up this
 17 document, or did someone else write it?

18 A. Someone else wrote it up. I
 19 don't remember who exactly.

20 Q. Do you -- and you don't recall
 21 who?

22 A. No.

23 Q. Okay. And what -- you
 24 referenced an IS computer system.
 25 Did that system have a name?

Page 194

1 A. That -- that would be our order
2 entry system.
3 Q. So the order entry system, was
4 that the JD Edwards system?
5 A. Yes.
6 Q. And so as part of the computer
7 code in this JD Edwards system, you would
8 have this formula that got applied to all of
9 the orders?
10 A. That's correct.
11 Q. Okay. And so if an order
12 wasn't flagged by application of this
13 algorithm, that order didn't get examined or
14 looked at; is that correct?
15 A. That's correct.
16 Q. Okay. So if your -- if your
17 algorithm was faulty or had a gap or was
18 missing something, then, you know,
19 potentially orders that were problematic
20 could get through; is that fair?
21 MR. TSAI: Objection.
22 THE WITNESS: That's a
23 possibility.
24 QUESTIONS BY MR. KAWAMOTO:
25 Q. In other words, your suspicious

Page 195

1 order -- your enhanced suspicious order
2 monitoring program was, you know, only as
3 good or as bad as this algorithm was; is that
4 fair?
5 A. That would be --
6 MR. TSAI: Object as to form.
7 QUESTIONS BY MR. KAWAMOTO:
8 Q. And who was -- other than you,
9 who helped develop this algorithm?
10 A. Everybody on the team was --
11 had input on what they felt, and that was
12 part of the -- the team that was put together
13 to work on what we felt should be in the --
14 in the order entry -- what we should put in
15 the order entry system or this suspicious
16 order program.
17 So Cathy Stewart, Sue Marlatt
18 was probably involved in it, myself, Karen
19 Harper, and, like I said, IT would probably
20 have -- would have had somebody in there at
21 the point where we would need them as far as
22 advising us what was possible.
23 And then we would write up the
24 document that we wanted to have put into the
25 system and submit that to IT for

Page 196

1 implementation, testing and so forth.
2 Q. And do you recall a memo ever
3 being drafted that would lay out this
4 algorithm and how it worked, or was it just
5 computer code that was put into the computer
6 program?
7 A. There was probably a document.
8 I don't know -- I don't remember where the
9 document -- if -- who had it, but the
10 document had to be developed to give to IT.
11 They had a -- they had a form that had to be
12 filled out and submitted to them for
13 evaluation and coding and amount of resources
14 needed and time needed to do the
15 implementation.
16 Q. And do you recall -- did this
17 form have a name?
18 A. I don't recall.
19 (Mallinckrodt-Rausch Exhibit 7
20 marked for identification.)
21 QUESTIONS BY MR. KAWAMOTO:
22 Q. Okay. So I would like to mark
23 as Exhibit 7 another document. It bears a
24 Bates number MNK-T1_477900.
25 So if you could take a minute

Page 197

1 to review this document and let me know when
2 you're done.
3 And I have -- I mean, it's a
4 relatively lengthy document, so I have, you
5 know, specific questions relating to certain
6 portions of it.
7 A. Do you want me to read all of
8 it?
9 Q. No.
10 Have you read the first half?
11 A. Yes, I've --
12 Q. Okay.
13 A. -- scanned through it, yes.
14 Q. So have you ever seen this
15 document before?
16 A. I don't remember it.
17 Q. Okay. Now, is my understanding
18 correct that this document is, to some
19 extent, a chronology or a timeline of the
20 development of the enhanced suspicious order
21 monitoring program?
22 A. It looks like it, yes.
23 Q. Okay. And at the very top it
24 says, "Activities 08/2008 through 08/2010."
25 Do you see that?

<p style="text-align: right;">Page 198</p> <p>1 A. Yes.</p> <p>2 Q. Okay. And the suspicious --</p> <p>3 the enhanced suspicious order monitoring</p> <p>4 program with its revised algorithm launched</p> <p>5 in the fall of 2009; is that correct?</p> <p>6 A. Correct.</p> <p>7 Q. Okay.</p> <p>8 A. Oh, Robyn McHale was the person</p> <p>9 that -- from IT that worked on it. She was a</p> <p>10 freelance IT person.</p> <p>11 You know what that is, right?</p> <p>12 Q. Actually, I don't. I'm sorry.</p> <p>13 A. Okay. It's a person that</p> <p>14 worked independently for themselves and then</p> <p>15 we would hire them to do work for us.</p> <p>16 Q. Essentially like a consultant;</p> <p>17 is that fair?</p> <p>18 A. Yeah, that would be a name for</p> <p>19 it.</p> <p>20 Q. And did she have a -- did she</p> <p>21 have a Mallinckrodt e-mail, a Mallinckrodt</p> <p>22 account?</p> <p>23 A. At that time she probably did,</p> <p>24 but I don't know if she still works with</p> <p>25 Mallinckrodt or not.</p>	<p style="text-align: right;">Page 200</p> <p>1 A. The IS department, I would say,</p> <p>2 would have that.</p> <p>3 Q. Okay. Okay. So directing your</p> <p>4 attention to page 2 of this timeline.</p> <p>5 A. Okay.</p> <p>6 Q. Do you see there's an entry</p> <p>7 involving you, it's 03/02/2009?</p> <p>8 A. Okay.</p> <p>9 Q. And it says, "Jim Rausch</p> <p>10 continues work with IS to define the criteria</p> <p>11 of what would be a peculiar order and how to</p> <p>12 determine programmatic flags for detection."</p> <p>13 Is that accurate?</p> <p>14 A. Yes.</p> <p>15 Let me explain this. I was --</p> <p>16 at the time I was fairly new to dosage, and</p> <p>17 Cathy was fairly new to bulk, so she was</p> <p>18 working with the dosage log rhythms {sic} and</p> <p>19 I was working on the bulk, because she had</p> <p>20 more experience on the dosage side.</p> <p>21 Q. And then it says, "CSR</p> <p>22 managers," that would have been you and</p> <p>23 Cathy?</p> <p>24 A. Where are we at?</p> <p>25 Q. The entry below that?</p>
<p style="text-align: right;">Page 199</p> <p>1 Q. Do you know if she had an</p> <p>2 office at Mallinckrodt?</p> <p>3 A. She had a cubicle, yes. I</p> <p>4 believe she did. Either -- at times she</p> <p>5 worked from her home, too, but -- I think she</p> <p>6 did, but I don't remember anymore.</p> <p>7 Q. Okay. And she would have been</p> <p>8 the person --</p> <p>9 A. She was one of the people that</p> <p>10 I remember from IS that was working on</p> <p>11 implementing this into the JD Edwards system.</p> <p>12 Q. And so she would likely have</p> <p>13 the document that set out what the exact</p> <p>14 algorithm was?</p> <p>15 A. She could be, but I would say</p> <p>16 that would -- probably since she was a</p> <p>17 consultant, she would not be the person that</p> <p>18 would -- that would have it now. It would</p> <p>19 probably reside with somebody in IT that</p> <p>20 actually worked for Mallinckrodt.</p> <p>21 Q. Okay. And that person would</p> <p>22 likely have the -- not only the enhanced</p> <p>23 suspicious order monitoring algorithm as of</p> <p>24 2009, but all the variations of it up until</p> <p>25 present; is that correct?</p>	<p style="text-align: right;">Page 201</p> <p>1 A. Oh.</p> <p>2 Q. "The CSR managers begin review</p> <p>3 of customer segmentation categories within</p> <p>4 the order entry system to determine if</p> <p>5 separate algorithms to define peculiar order</p> <p>6 patterns will be necessary based on a class</p> <p>7 of trade."</p> <p>8 A. Correct.</p> <p>9 Q. Do you know what the final</p> <p>10 determination of that was?</p> <p>11 A. That we probably would have</p> <p>12 separate needs depending on our customers.</p> <p>13 Q. So this means that you would</p> <p>14 have separate algorithms depending on the</p> <p>15 class of customer?</p> <p>16 A. What it means is based upon our</p> <p>17 business needs, okay. What we did for dosage</p> <p>18 may be different from what we do for bulk as</p> <p>19 far as what we implemented.</p> <p>20 Q. Okay. But within the dosage</p> <p>21 algorithm --</p> <p>22 A. Yeah.</p> <p>23 Q. -- it was not further</p> <p>24 subdivided into different classes of</p> <p>25 customers?</p>

Page 202

1 A. No.

2 Q. So you had one -- you had

3 one -- for dosage products, you had one

4 algorithm that was applied to wholesalers,

5 distributors, retail pharmacies?

6 A. Correct.

7 Q. The same algorithm?

8 A. If I remember. Again, I didn't

9 develop, but I believe so.

10 Q. Okay. And then do you see

11 6/29/2009, it says, "Revised customer

12 questionnaires are submitted to legal that

13 have been updated based upon CSR focus group

14 meetings Jim Rausch and Cathy Stewart

15 conducted with CSRs"?

16 A. Yes, I see that. Okay.

17 Q. What is that in reference to?

18 A. It was a questionnaire that I

19 think we worked on, but I'm not sure if we

20 ever did -- what it composed of. I don't

21 remember it.

22 Q. And so are you not sure whether

23 it was ultimately ever sent out?

24 A. Correct. I'm not sure what we

25 did with that.

Page 203

1 Q. And it says, "CSR focus group

2 meetings."

3 What -- do you recall what the

4 focus group meetings were?

5 A. No, I don't.

6 Q. Okay. Now, it says 7/2009,

7 "CDIG begin sending out SM customer

8 questionnaires."

9 What is "CDIG"?

10 A. Customer data integrity group.

11 Q. And you don't know whether they

12 sent out revised questionnaires or the old

13 questionnaires?

14 A. No, you would have to ask

15 somebody in that group.

16 Q. Okay. Now, do you see at the

17 top of page 3 it says, "Work continues with

18 IS on algorithms."

19 A. Uh-huh.

20 Q. "E-mail follows from Cathy

21 Stewart."

22 A. Right.

23 Q. And can you review that e-mail

24 for me?

25 MR. TSAI: Dean, after we go

Page 204

1 through the top e-mail, can we take a

2 break?

3 MR. KAWAMOTO: Sure.

4 THE WITNESS: Okay. So this

5 was an e-mail -- or this was what I

6 believe -- oh, okay. It is from

7 Cathy.

8 Cathy, like I said, was working

9 on the formulas for the dosage

10 business, and I think this was --

11 somebody says -- this doesn't make

12 sense.

13 E-mails from Cathy. I'm

14 getting confused.

15 I'm not sure if that's Karen

16 that's saying that, but --

17 QUESTIONS BY MR. KAWAMOTO:

18 Q. Well, the top line says, "work

19 continues with IS on algorithms, e-mail

20 follows from Cathy Stewart."

21 A. Right.

22 Q. And it -- that seems to

23 indicate that Cathy Stewart is saying --

24 A. Okay. Cathy Stewart sent an

25 e-mail to Robyn. "I'm sorry to ask this

Page 205

1 again, but my notes -- aren't very clear.

2 This is a correct ship to report classes on

3 this report is for total quantity."

4 I think she was reviewing

5 with -- what Robyn had presented to her and

6 Cathy was just questioning if that's what she

7 had asked for or not.

8 Q. Okay. And then -- well, do you

9 see the paragraph in the middle of the page

10 that starts with, "This was -- this was we

11 can see that this customer"?

12 Do you see that?

13 A. Uh-huh.

14 Q. And then it's below the -- what

15 appears to be both months and, I guess,

16 hypothetical orders.

17 Do you see that?

18 A. Yes.

19 Q. Okay. So what -- what is

20 Cathy's concern?

21 A. I'm not sure. You would have

22 to ask Cathy about that.

23 Q. Okay.

24 A. From -- this was -- okay. I

25 think her -- what she was saying that

Page 206

1 their -- their gradual increase of orders
2 rather than jumping from 100 to 200 would
3 trigger the 2 X formula versus if they
4 gradually increase from 100 to 125 to 150 to
5 175 would not trigger that -- that to kick
6 out.
7 Q. In other words, it would be
8 possible over time to actually have a
9 significant increase in the monthly order
10 that wouldn't be triggered by the algorithm;
11 is that fair?
12 A. Right. And I think that's what
13 Cathy is pointing out --
14 Q. Okay.
15 A. -- is that they could get
16 around it that way. So we were trying to
17 work on a system that everything that we
18 possibly could think of of getting around
19 placing an order that we didn't feel it was
20 legitimate, we were trying to think of
21 everything possible.
22 Q. And so how was this concern
23 addressed?
24 A. I don't remember. I think it
25 was addressed, but I don't remember exactly

Page 207

1 how.
2 Q. Okay. And so it was possible
3 that it -- was it possible that it wasn't
4 addressed?
5 A. I think you would have to talk
6 to Cathy about that.
7 Q. Okay. Do you know --
8 A. Like I said, she was working on
9 the dosage log rhythms {sic} and I was
10 working on the bulk because that's what we
11 were familiar with.
12 Q. Do you know if anyone else
13 raised a similar concern, namely that you
14 could have gradual increases that over time
15 result in a significant increase that
16 wouldn't be caught?
17 A. If anybody else --
18 Q. Yeah, do you know if this
19 concern was raised by anyone else?
20 A. I'm not sure. It could have
21 been. I mean, the team working on this was
22 looking at all possibilities. They're trying
23 to think of what they could do, somebody -- a
24 customer could do to try and get around the
25 system.

Page 208

1 Q. But -- but you're not aware
2 of -- you're not aware of what fix, if any,
3 was applied to address this concern?
4 A. No.
5 MR. KAWAMOTO: Okay. So why
6 don't we take a break now.
7 VIDEOGRAPHER: We're going off
8 the record at 2:35 p.m.
9 (Off the record at 2:35 p.m.)
10 VIDEOGRAPHER: We are back on
11 the record at 2:51 p.m.
12 QUESTIONS BY MR. KAWAMOTO:
13 Q. So if we could return to the
14 document that you were just looking at, I
15 believe it is Exhibit 7.
16 A. Okay.
17 Q. Okay?
18 Now, you had -- we were
19 discussing the gradual increase in orders
20 over time, and you had indicated that's
21 something that Cathy Stewart would be
22 knowledgeable about in the dosage area.
23 A. That's correct.
24 Q. With respect to the bulk area,
25 which was your area of expertise, wouldn't

Page 209

1 that same problem also apply?
2 A. Yeah, the same problem could
3 apply, yes.
4 Q. And so how was that addressed
5 in the bulk context?
6 A. I don't remember, but I'm
7 sure -- is it in here? We would have put
8 something in based upon the bulk side also.
9 I don't remember exactly what it was.
10 Q. Well, how -- how would one fix
11 this problem?
12 A. How would one fix this problem?
13 Q. Yes. I mean, hypothetically,
14 how would you fix a problem? I mean, if you
15 have a numeric formula that's based on
16 looking at a current order and then comparing
17 it to sort of prior order history, I mean,
18 how would you -- how would you modify the
19 formula to address that problem?
20 A. It would probably be based upon
21 an average versus looking at -- and I'm just
22 guessing at this point because I don't
23 remember anymore. I'll just leave it at
24 that: I don't remember anymore how we
25 addressed it.

Page 210

1 Q. But mathematically speaking,
2 what -- I mean, what would you do? Because,
3 I mean, you're already basing that formula on
4 an average, aren't you?
5 A. Correct. Average period of
6 time of ordering.
7 Q. Yes.
8 A. Yes.
9 So if they went from 100 to 150
10 to 175 to 200 over a period of time, I guess
11 you would try to divide that and come up with
12 an average. And if it went two times over
13 that average, it might kick it out that way.
14 Q. Well, I mean, isn't the only
15 way to decrease the two times -- so instead
16 of looking at two times, you would look at,
17 for example, 1.5?
18 A. That's one approach. I'm not
19 sure if that's the only approach.
20 Q. Well, what -- what -- what is
21 the other approach that you're --
22 A. I think -- that's what I was
23 just talking about. If you looked at the
24 average of, say, 125, 150, 175, 200, which is
25 a general increase, if you took that average

Page 211

1 and say it was 150, if the orders were two
2 times that 150, then it would kick it out.
3 That's one way of doing it.
4 Or you could do it like you
5 said and make it 1.5 or 1.75 or 2 or --
6 there's probably a number of ways of doing it
7 besides that, but I don't remember what we
8 landed on.
9 Q. And in terms of the average,
10 though, you would -- so you would -- you
11 would try to shorten the average period --
12 I'm just trying to understand how modifying
13 the average --
14 A. I understand what you're --
15 what you're asking, but I don't remember what
16 we did.
17 Q. Okay. And to be clear, you're
18 not even sure that this problem was
19 addressed, are you?
20 A. I don't remember.
21 Q. So turning to page 4, at the
22 very top it says, "Work continues with IS
23 peculiar order report being generated based
24 upon algorithm settings that's 49 pages
25 long."

Page 212

1 Do you see that?
2 A. Uh-huh.
3 Q. So how long was the peculiar
4 order report that you ultimately ended up
5 reviewing after the program went live in fall
6 of 2009?
7 A. It varied from day to day. On
8 an average, I would say it's less than
9 probably -- probably 10 or 15.
10 Q. And that's 10 or 15 pages?
11 A. Yes.
12 Q. And how many orders would be on
13 that report?
14 A. Maybe five or so orders on a
15 page.
16 Q. So anywhere from 25 to 50
17 orders; is that fair?
18 A. It could be on a day, daily
19 basis.
20 Q. And who was responsible for
21 investigating and determining whether there
22 was a valid business -- well, strike that.
23 What did you do with those 25
24 or 50 orders that would show up on your
25 report on a daily basis?

Page 213

1 A. I would review them to see if
2 there's anything that I saw that would kick
3 that order out, because it would give us
4 different histories of that particular
5 customer and what they ordered and that type
6 of thing. And if I could see something that
7 would validate the order that was flagged, I
8 would let the order go.
9 If I couldn't validate it, then
10 I would go to the CSRs like I explained
11 earlier, the process, CSR, business manager,
12 sales rep, and try to get this explained.
13 Q. And were you doing all 25 to 50
14 orders, or was someone else also doing orders
15 for you?
16 A. I was doing it.
17 Q. So you were the only one
18 essentially doing it?
19 A. Reviewing that.
20 And it could -- it could have
21 been less. I don't remember particularly.
22 It could have been five. I don't know, five
23 to ten, if that many.
24 Q. And roughly how long did it
25 take you? What's your -- well, strike that.

Page 214

1 What's your recollection as to
2 how long it took you?
3 A. A couple hours a day.
4 And that didn't entail -- if
5 I couldn't -- if I couldn't come up with a
6 solution of bringing it to the business
7 manager or to the sales rep, we tried to get
8 it resolved as soon as possible, hopefully by
9 the -- the end of the day, if possible. If
10 not, it may take a day or two to be resolved,
11 depending on where the sales person was or
12 where the business manager -- if I couldn't
13 get ahold of them right away. But those were
14 not that many orders.
15 Q. And so what's the maximum that
16 you could review, the maximum number of
17 orders that you could review at any day?
18 A. The maximum that I could
19 review?
20 Q. Well, I mean, would it be
21 possible for you to review 200 orders?
22 MR. TSAI: Object to the form.
23 THE WITNESS: No, but to answer
24 your -- to answer that, I would say
25 there was not the case where I was

Page 215

1 being asked to -- or seeing 200 orders
2 on a daily basis.
3 QUESTIONS BY MR. KAWAMOTO:
4 Q. Was there anyone else at the
5 company other than you that could review
6 these orders?
7 A. Yes. As I mentioned before,
8 the customer service rep that sat in for me
9 when I was not there.
10 Q. But as a general matter, it was
11 just you reviewing these orders?
12 A. Correct.
13 Q. And did you have other job
14 responsibilities in addition to reviewing
15 these orders?
16 A. Yes.
17 Q. What were they?
18 A. I oversaw the customer service
19 group. I had a pretty -- pretty senior
20 group, so just solving problems or questions
21 that they may have, meeting with other people
22 on other business on a daily basis. But this
23 was -- this was primary in the morning and
24 the afternoon.
25 Q. Well, it was -- if it was

Page 216

1 primary in the morning and the afternoon --
2 A. Right. That's when the reports
3 came out.
4 Q. Okay. And so did they come out
5 twice daily?
6 A. I believe they did, yes.
7 Q. And if this was primary for the
8 morning and this was primary for the
9 afternoon --
10 A. It took up a good bit of my
11 time.
12 Q. Yes.
13 When did you have time to get
14 your other work done?
15 MR. TSAI: Object to the form.
16 THE WITNESS: Could you be more
17 specific?
18 QUESTIONS BY MR. KAWAMOTO:
19 Q. Sure.
20 If this was your primary task
21 in the morning and your primary task in the
22 afternoon -- I mean, the working day is
23 generally just divided into morning and
24 afternoon --
25 A. Right.

Page 217

1 Q. -- so --
2 A. Yeah, we're talking an hour or
3 so in the morning and an hour or so in the
4 afternoon of reviewing these orders.
5 Q. And so do you see the entry,
6 that 10/27/09, "peculiar order report being
7 generated based on algorithm is 150 dosage
8 orders per day and 170 bulk API orders per
9 day"?
10 A. I see that.
11 Q. Okay. Would it have been
12 possible for you to review 150 dosage orders
13 per day?
14 A. No, it would not.
15 Now, keep in mind this was
16 based upon the working document, or what we
17 were looking at as far as suspicious order
18 monitoring program based upon different
19 criteria.
20 Now, as we went along, there
21 was some things that were not working that
22 created this problem of having so many. That
23 had nothing to do with what we wanted to look
24 at, but it was put into the system.
25 And I think you can say there

Page 218

1 was some statistical problems that needed to
2 be fine-tuned. So it was kicking out orders
3 that shouldn't have been kicked out.
4 And this was an IS -- this was
5 an IS issue.
6 Q. And what is your basis for
7 saying that it was kicking out orders that
8 shouldn't have been kicked out?
9 Well, let me rephrase that.
10 What are examples of orders that were being
11 kicked out that shouldn't have been?
12 A. Well, right here, I don't
13 remember exactly what this was about, where
14 it says, "The 30-day cumulative algorithm is
15 turned off because that specific trigger was
16 not spelled out in HDMA guidance and has
17 inflated the peculiar order count."
18 So that's one instance where it
19 was inflating the number of orders that we
20 were looking at.
21 Q. And what is the 30-day
22 cumulative algorithm? Do you know what that
23 is?
24 A. I don't remember.
25 Q. Now, from this entry, it

Page 219

1 indicates that the 30-day cumulative
2 algorithm was not spelled out in HDMA
3 guidance. But that's not the same thing as
4 saying that this algorithm wasn't going to
5 provide valuable information on peculiar
6 orders, is it?
7 MR. TSAI: Object to the form.
8 THE WITNESS: No, I don't think
9 it's saying that. I'm not sure what
10 it's saying there.
11 QUESTIONS BY MR. KAWAMOTO:
12 Q. Okay. Was there any analysis
13 done on the impact of removing the 30-day
14 cumulative algorithm with respect to the
15 orders that were no longer being kicked out?
16 A. Well, as I had mentioned
17 earlier, you know, what we did was we -- we
18 test ran this and massaged it as it went
19 along to see if it was doing the job we
20 wanted it to do as far as looking at the
21 orders based upon what we felt was needed,
22 and it was adjusted as we went along. So
23 that's all I can -- all I can remember.
24 Q. So with respect to this 30-day
25 cumulative algorithm --

Page 220

1 A. Uh-huh.
2 Q. -- when you have it -- when you
3 have it turned on, it is kicking out, you
4 know, some amount of orders. Or I guess to
5 put it more accurately, it's flagging a
6 certain amount of orders as peculiar; is that
7 correct?
8 A. Correct.
9 Q. And then when you remove this,
10 when you turn it off, those orders are no
11 longer flagged as peculiar; is that right?
12 A. Correct.
13 Q. Was any analysis ever done to,
14 you know, verify or confirm that those orders
15 were in fact not peculiar?
16 A. I don't remember.
17 Q. If that analysis were done, who
18 would have it?
19 A. I'm not sure who would have it
20 at this time.
21 Q. Now, as a practical matter, you
22 can't review 150 orders per day, correct?
23 A. That would be difficult.
24 Q. And so if you had a program
25 that were -- that was identifying 150 orders,

Page 221

1 just as a matter of resources, you would have
2 to tweak that; isn't that correct?
3 A. And I think that's what this is
4 showing here, is we were tweaking things that
5 we felt that we could tweak without losing
6 focus of what we intended to do.
7 And again, we weren't given any
8 guidance on what it should be doing, but we
9 felt we still had a pretty robust system, and
10 just 150 orders were not within our -- our --
11 able to do that at that time. So we felt by
12 changing this we could still maintain a
13 robust system.
14 Q. But part of what you were
15 looking at in terms of designing this system
16 was its ability to function given the
17 resources that were assigned to it; is that
18 fair?
19 A. I'm not sure if that's fair.
20 We felt we -- we still felt with our end
21 product that we had a good product, and with
22 the resources that we had that we could
23 manage it.
24 Q. Well, with respect to, for
25 example, this 30-day cumulative algorithm, no

Page 222

1 one ever went back and actually reviewed the
2 orders that were no longer being kicked out
3 because the algorithm was turned off?
4 A. I didn't say that. I said I
5 don't remember if somebody did or not.
6 Q. Do you feel that analysis
7 should have been done before turning it off?
8 A. It probably should have and
9 probably was; I just don't remember.
10 Q. And you don't know who would
11 have done that analysis or how it would have
12 been memorialized?
13 A. No, I don't.
14 Q. Then do you see down it says --
15 the entry is 4/30/2010?
16 A. Yes.
17 Q. It says, "Peculiar order
18 calculation change from two times factor to
19 three times factor."
20 A. Okay.
21 Q. Is that consistent with your
22 recollection of how the algorithm was
23 modified?
24 A. Yes.
25 Q. Okay. What was the basis for

Page 223

1 changing it from two times to three times?
2 A. This -- the system had been
3 implemented already. I believe it was the
4 fall of 2009, right?
5 Q. I believe that's what you said.
6 A. Yeah.
7 So after months of working with
8 it and not finding any peculiar orders became
9 suspicious orders, we felt pretty -- pretty
10 good about changing the number from 2 X to 3
11 X. So that's what we did.
12 And we ran that -- I ran that
13 by Karen Harper, and Karen Harper agreed to
14 that based upon us not having any suspicious
15 orders, and we put that in place.
16 Q. And -- well, why three times
17 instead of [REDACTED] times or 4 times?
18 A. That's the number that we came
19 up with.
20 Q. And so sort of going back to a
21 previous question that I've asked.
22 A. Uh-huh.
23 Q. With respect to the change from
24 two times to three times, you know,
25 presumably there are now orders that are --

Page 224

1 that would have been kicked out under the two
2 times that were not kicked out under three
3 times; is that correct?
4 A. That's true.
5 Q. Was there ever a trial run or
6 an analysis done to confirm that those orders
7 were not in fact peculiar?
8 A. On the ones that didn't kick
9 out?
10 Q. Yes, on the ones that were no
11 longer kicked out because of this
12 programmatic change.
13 A. I don't remember. I don't know
14 if we did or not.
15 Q. Okay. But you believe that is
16 an analysis that should have been done; is
17 that correct?
18 A. We probably did it, yes, but I
19 don't remember exactly who did it or when it
20 was done.
21 Q. Now, one of the things about
22 increasing the factor from two times to three
23 times is that it does -- it does -- well,
24 strike that.
25 Do you recall Ms. Stewart's

Page 225

1 concern about a gradual -- gradual increases
2 that was referenced on page 3 of this
3 document?
4 A. Yes, I remember. Yes.
5 Q. Okay. So when you go from a
6 two times to a three times factor, that is
7 going to increase that concern or that risk,
8 isn't it?
9 A. I -- yes.
10 Q. Okay. And so in this regard,
11 with respect to this risk, meaning a gradual
12 increase over time, this calculation is now
13 less protective than it would have been if it
14 were two times?
15 A. That's -- that's true. But
16 keep in mind, we were not -- we were not
17 the -- selling to the end user in that. Not
18 only were we -- we weren't -- we were selling
19 this material to the distributors and -- who
20 had their own programs in place, and they
21 were also responsible for reviewing the
22 orders and customers that they were selling
23 to.
24 So we felt even with the 2 X,
25 where we weren't finding any issues with

Page 226

1 orders that we couldn't explain, and we -- we
2 changed our process to the 3 X and continued
3 to monitor. And we changed it to 3 X, and we
4 still didn't have any peculiar orders that
5 became suspicious orders.
6 Q. Well, by --
7 A. But we felt comfortable in
8 doing this at the time.
9 Q. By changing the formula from
10 2 X to 3 X?
11 A. Right. And we discussed that,
12 yes.
13 Q. Yes.
14 And it would -- it would -- I
15 mean, well, one of the effects is that it
16 decreased the number of orders you were
17 reviewing, yes?
18 A. That's true.
19 Q. Do you recall how much of a
20 decrease this was?
21 A. I don't -- I don't remember.
22 Q. Now, you indicated in your
23 prior answer that -- well, strike that.
24 Is it fair to say that part of
25 the reason Mallinckrodt was comfortable

Page 227

1 making this change from 2 X to 3 X is
2 because, as you indicated, the distributors
3 have their own programs for suspicious
4 orders?
5 A. Well, that was part of it.
6 Part of it was that we had not found any
7 peculiar orders that became suspicious
8 orders. And as we changed it to 3 X and we
9 had approval to do that, or I had approval to
10 do that, we continued to monitor orders,
11 peculiar orders, and again, we did not have
12 any suspicious orders.
13 Q. What did you do to -- well,
14 what did Mallinckrodt do to satisfy --
15 satisfy itself that the distributors were
16 implementing adequate SOM programs?
17 A. I wasn't -- I was just there at
18 the beginning of this, but -- I should say,
19 actually it probably started in 2009, but
20 there was a team that was put together of
21 Karen Harper and one of the legal people
22 along with -- who would do audits with the
23 distributors to see what programs they had in
24 place.
25 Q. Now, if I could direct your

Page 228

1 attention to page 7 of this memo, you see at
2 the very bottom of the page it says, "Action
3 plan"?
4 A. Okay.
5 Q. And in the middle of that
6 paragraph at the very bottom it says, "The
7 team believes the suspicious order monitoring
8 program can be further enhanced by analyzing
9 chargeback data for indirect customers and
10 direct sales information available within
11 existing systems."
12 Do you see that?
13 A. I do.
14 Q. Do you know if the suspicious
15 order monitoring program was ever modified to
16 take -- to analyze chargeback data?
17 A. Yes, it was. As part of our
18 ongoing enhancement program for the
19 suspicious order program, it was identified
20 that the chargeback system could help us in
21 identifying who the distributors were selling
22 to. So eventually in 2010, this was -- the
23 monitoring of suspicious orders were moved
24 over to the chargeback team.
25 Q. And do you recall when in 2010

Page 229

1 this occurred?
2 A. Fall of 2010.
3 Q. And so were you still involved
4 in the suspicious order monitoring program at
5 that point?
6 A. The daily review was turned
7 over to that department.
8 Q. So what you had previously
9 described about how you would get 50 orders
10 and then you would contact the --
11 A. Right.
12 Q. -- sales reps, that was no
13 longer your responsibility?
14 A. Correct. It was turned over to
15 this other group that had the chargeback
16 information.
17 Q. Okay. And do you know who in
18 this other group it was turned over to?
19 A. Tiffany is who I had mentioned
20 earlier. I don't remember her last name.
21 Q. Okay. And do you know what
22 procedure or process she followed?
23 A. No, I don't.
24 Q. Do you know if she continued to
25 review these reports on a daily basis?

Page 230

1 A. I believe she did, yes.
2 Q. And she continued to
3 communicate with the sales reps?
4 A. I would imagine that would be
5 part of her process. I'm not sure what she
6 did once she took over it, but I explained to
7 her what I did and -- as far as what my
8 review -- what review I took as far as
9 talking to the sales reps and the business
10 managers. And they also had the chargeback
11 system in that group, so I'm sure it was used
12 to enhance the system.
13 Q. And you indicated that --
14 A. And I turned over all my files
15 over to her -- for her, to her group.
16 Q. And do you know how she used
17 the chargeback data?
18 A. I don't.
19 Q. Now, prior to 2010, did you
20 have access to the chargeback data?
21 A. I did not, no.
22 I think it was identified as a
23 source that we could implement to enhance our
24 system as we were looking for opportunities
25 for more information and that. That was

Page 231

1 pointed out as, hey, maybe we can use the
2 chargeback system.
3 Q. Well, how old is the chargeback
4 system?
5 A. It's been around for a long
6 time.
7 Q. So in 2008 and 2009, you had
8 chargeback data; is that correct?
9 A. We did.
10 Q. And so in -- so in theory, one
11 could have used this chargeback data, you
12 know, in 2007 or 2008 or 2009?
13 A. In theory it could have.
14 Q. So it's not as if Mallinckrodt
15 was collecting now data starting in 2010; it
16 was that it was using the data it had?
17 A. Yes, and we -- I don't remember
18 exactly how we -- you know, we finally
19 figured out, hey, maybe we can start, you
20 know, digging deeper into the -- into who our
21 customers were selling to also as part of an
22 enhancement.
23 (Mallinckrodt-Rausch Exhibit 8
24 marked for identification.)
25

Page 232

1 QUESTIONS BY MR. KAWAMOTO:
2 Q. So I'm marking another exhibit.
3 It is Exhibit 8.
4 A. Are we done with this one?
5 Q. Yes, we're done with that one.
6 And this has Bates number
7 MNK-T1_264431.
8 A. Okay.
9 Q. Okay. Now, just as a matter of
10 chronology, the enhanced -- the enhanced SOM
11 program came online in 2000 -- in the fall
12 of 2009?
13 A. Yes.
14 Q. And in fall of 2010, your SOM
15 responsibilities were transferred to Tiffany?
16 A. That's correct.
17 Q. So you oversaw the enhanced SOM
18 program for dosage products for one year?
19 A. Correct.
20 Q. Okay. This document, it's
21 Bates-numbered MNK-10-1_264431 {sic}, and it
22 purports to describe the peculiar order
23 process.
24 A. Okay.
25 Q. Based on your review, does this

Page 233

1 accurately describe what Mallinckrodt's
2 peculiar order process was from fall of 2009
3 to fall of 2010?
4 A. As -- as a peculiar order, yes.
5 Q. Okay. And then you'll note
6 that someone --
7 A. This is what I was trying to
8 describe to you earlier but probably didn't
9 do a very good job of it, where it summarizes
10 the API of the product.
11 Q. Okay. And you'll see how
12 the -- in the peculiar order criteria, the 2
13 has been crossed out and someone has
14 substituted 3 in there.
15 A. Okay.
16 Q. So this would suggest that this
17 document was -- would have been prepared
18 sometime in 2010, because that's when that
19 decision was made?
20 A. Sometime in that time frame,
21 yes.
22 Q. Okay. Now, it says, "New
23 customers for dosage. Dosage will manually
24 establish the threshold limit."
25 What -- what is the threshold

Page 234

1 limit?

2 A. I believe the threshold limit,

3 if I remember right, was based upon the

4 customer class of what the average order

5 amount was for that -- a customer of that

6 type.

7 Since we had no previous orders

8 from this customer, we -- we just took the

9 average of what we were selling to customers

10 like -- like them so we had some kind of

11 basis to go on.

12 Q. And when you say "customer

13 class," what do you mean by that?

14 A. Like distributor.

15 Q. So distributor verse wholesaler

16 verse chain pharmacy, are those the different

17 classes?

18 A. I would say so, yes.

19 Q. And the threshold limit is

20 essentially -- it's the base that the

21 algorithm would compare the current order to

22 sort of the historic baseline; is that

23 accurate?

24 A. Yes.

25 Q. So for the threshold -- well,

Page 235

1 strike that.

2 So one of the problems could be

3 if your threshold limit were set too high,

4 then, you know, orders that should be tagged

5 as peculiar would not be; is that fair?

6 A. That's possible.

7 Q. All right. Now, you indicated

8 that the threshold limit was set based on the

9 average of all of the distributors.

10 A. I believe so. I think that's

11 how it was done, yes.

12 Q. And for the distributors, was

13 this -- was this average set on an

14 industry-wide assessment of distributors, or

15 was it just Mallinckrodt's distributor

16 customers?

17 A. Mallinckrodt's.

18 Q. Okay. Now, distributors varied

19 in size and geographic scope, didn't they?

20 A. I think we tried to take in

21 effect how many -- how many different

22 distributing warehouses they had, what their

23 typical sales were, that type of thing, all

24 the information that we could gather, and

25 tried to make them comparable to customers

Page 236

1 that we already had on the books and get an

2 average based upon that as our criteria to

3 start with.

4 Q. Okay. So it sounds like you

5 had distributor subclasses, essentially?

6 A. Yes.

7 (Mallinckrodt-Rausch Exhibit 9

8 marked for identification.)

9 QUESTIONS BY MR. KAWAMOTO:

10 Q. Okay. So I'd like to mark as

11 Exhibit 9 the following document, and this

12 has a Bates number MNK-T1_269399.

13 A. Okay.

14 Q. Okay. So this is a memo dated

15 November 2, 2010, to Karen Harper from Howard

16 Davis.

17 A. Okay.

18 Q. Do you know who Howard Davis

19 is?

20 A. I believe he was with the DEA.

21 Q. Okay. And did you ever work

22 with Howard Davis on anything while you were

23 at Mallinckrodt?

24 A. No, I didn't. Not that I

25 remember.

Page 237

1 Q. Okay. Do you know anything

2 about Howard Davis other than he was with the

3 DEA?

4 A. No.

5 Q. Okay. So in this memo he

6 states -- well, let's start with the second

7 full paragraph.

8 A. Okay.

9 Q. He states, "Federal register

10 notices published as early as 2007 state

11 specifically that using formulas that rely on

12 percentages or averages over time has been

13 determined by the DEA to be insufficient."

14 Do you agree with that

15 statement?

16 A. Yes.

17 Q. Then skipping to the paragraph

18 below that, it says, "An order must not be

19 processed and filled if it's either

20 suspicious or excessive. The existing SOP

21 excels to meet this requirement through a

22 specific evaluation process; however, the

23 numeric formula is problematic. For example,

24 should an occasion arise where an order is

25 three times over the historical average for

Page 238

1 that customer, an item, or in a situation
2 where the order meets but does not exceed the
3 three times criteria, it would theoretically
4 be filled through normal processing without
5 question -- without further question. In
6 doing so in certain cases and as noted in
7 recent immediate suspensions of other
8 large-scale DEA registrants, which are all a
9 matter of public record, Mallinckrodt would
10 be unnecessarily exposing itself to potential
11 liability."
12 Do you see that paragraph?
13 A. I do.
14 Q. Do you agree with that
15 statement?
16 MR. TSAI: Object to the form.
17 THE WITNESS: I understand -- I
18 hear -- I hear what he's saying, yes.
19 QUESTIONS BY MR. KAWAMOTO:
20 Q. Well, and do you agree with his
21 assessment?
22 A. Well, we -- we felt that we
23 were -- we had done with the 2 X, that we
24 didn't -- as I told you before, we felt
25 comfortable with going from 2 X to 3 X, and I

Page 239

1 had Karen's approval. And apparently in due
2 diligence she talked to Howard Davis about
3 it, and in doing so, he was coming back
4 feeling that going from 2 X to 3 X would
5 be -- expose us to potential liability.
6 Q. Did you know that Karen Harper
7 talked to Howard Davis about the 2 X to 3 X
8 change?
9 A. I did not.
10 Q. Okay. If you had known that
11 Howard Davis had concerns about this 3 X
12 change, would it have -- well, strike that.
13 Did you support the change from
14 2 X to 3 X?
15 A. Yes, at the time I did.
16 Q. If you had known that Howard
17 Davis had concerns about changing it from 2 X
18 to 3 X, would that have mattered to your
19 support?
20 A. Of course it would have.
21 MR. TSAI: Object to the form.
22 THE WITNESS: Yes.
23 QUESTIONS BY MR. KAWAMOTO:
24 Q. Okay. And how would it have
25 mattered?

Page 240

1 A. We wouldn't -- we wouldn't have
2 changed it.
3 Q. Okay.
4 A. Keep in mind, we were -- you
5 know, we were on our own as far as developing
6 our programs. So, you know, Karen, on doing
7 her job as compliance manager, felt it was
8 important to keep the DEA in the progress of
9 our program that we had placed.
10 And I guess in seeing this --
11 and this is the first time I have seen it --
12 she apparently brought it to Howard's
13 attention that we had changed from 2 X to
14 3 X, and he apparently responded in this
15 manner.
16 Q. Okay. Now, turning to the
17 second page, it says, "Numeric formulas do
18 not identify circumstances that might be
19 indicative of diversion, such as ordering
20 larger quantities of a limited variety
21 regularly that would not otherwise be viewed
22 as suspicious, like ordering controlled
23 substances with few, if any, other drugs or
24 products, whether controlled or
25 noncontrolled, ordering highly abused

Page 241

1 controlled substances in limited quantities
2 disproportionate to other orders, or even
3 ordering the same controlled substances from
4 multiple suppliers."
5 Do you see that?
6 A. I see it.
7 Q. And do you agree that these are
8 all problems with numeric formulas?
9 A. These are all possibilities,
10 yes.
11 Q. Okay. And directing your
12 attention to Exhibit 2, so if you go back to
13 the start of the dep, which was that 2006 DEA
14 letter, these are the factors that the DEA
15 identified in that letter, aren't they?
16 A. Are you talking about the 10?
17 Q. I'm sorry, let me pull that
18 out.
19 Yes. If you look at Exhibit 2,
20 on page 3, Bates number 273565, it's the
21 circumstances that might be indicative of
22 diversion, and it lists out four different
23 things.
24 A. Oh. Yes, that's what he's
25 talking about there.

Page 242

1 Q. Okay. So these four things
2 match up to the concerns that Howard is
3 expressing?
4 A. Yes.
5 Q. And the DEA expressed these
6 concerns in 2006, didn't they?
7 A. It looks like it, yes.
8 Q. Okay. Then underneath that
9 there's another paragraph that says, "The DEA
10 registrant population as a whole is now
11 required to consider the totality of the
12 circumstances when evaluating an order prior
13 to it being filled."
14 Do you under -- do you agree
15 with that statement?
16 A. Yes.
17 Q. Okay. And underneath that,
18 skipping further down, it says, "While not
19 all-inclusive, recommended customer inquiries
20 may include such factors as," and then this
21 lists one, two, three, four, five, six, seven
22 eight, nine -- nine different bullet points.
23 Do you see those?
24 A. I do.
25 Q. And do you agree that all of

Page 243

1 these should be recommended customer
2 inquiries?
3 MR. TSAI: Object to the form.
4 THE WITNESS: Let me look --
5 read them.
6 QUESTIONS BY MR. KAWAMOTO:
7 Q. Sure.
8 A. Okay.
9 Q. Okay. So do you agree that
10 this is all information that should be taken
11 into account?
12 A. I believe this was part of that
13 checklist that was being sent out by the
14 credit department, or CDIG, on a yearly basis
15 for our customers to check whether they were
16 doing that or not.
17 Q. Okay. And so if Mallinckrodt's
18 SOM program was not taking into account this
19 information, you would view that as
20 problematic, would you not?
21 MR. TSAI: Object to the form.
22 THE WITNESS: I would. But
23 like I stated, I believe we were
24 sending this out when new customers
25 were being established. And on a

Page 244

1 yearly basis we were sending it out to
2 our customers asking these questions,
3 or similar questions, asking them if
4 they'd fill it out and send it back to
5 us for us to continue to sell to them.
6 QUESTIONS BY MR. KAWAMOTO:
7 Q. Do you know if any attempt was
8 made to verify the information that the
9 customers were providing in this regard?
10 A. I don't know.
11 Q. Okay. Should that information
12 have been verified given its importance?
13 A. I guess it would be.
14 (Mallinckrodt-Rausch Exhibit 10
15 marked for identification.)
16 QUESTIONS BY MR. KAWAMOTO:
17 Q. Now, this document also has an
18 attachment which I'm going to mark as
19 Exhibit 10, and the Bates number for this
20 attachment is MNK-T1_269401.
21 Now, actually, I'm sorry, if I
22 could interrupt you briefly.
23 So going back to Exhibit 9,
24 this memorandum.
25 A. Okay.

Page 245

1 Q. Do you know what steps, if any,
2 were taken to address Mr. Davis' concerns?
3 A. This was written in
4 November 2010, and I was no longer
5 responsible for monitoring the orders. But
6 like I mentioned earlier -- as far as the 2 X
7 and the 3 X. Okay?
8 And like I stated earlier, I
9 believe this was part of the checklist that
10 we sent out to our -- our customers from
11 CDIG.
12 Q. But you don't know if anything
13 was actually done to modify the enhanced SOM
14 program to respond to Mr. Davis' concerns?
15 A. I do not.
16 Q. Okay. Okay. So can you -- can
17 you review the MNK -- well, I'm sorry, can
18 you review Exhibit 10?
19 And I don't have detailed
20 questions on all of it, but I do have some
21 questions for you on this document.
22 A. Is there a date on this or --
23 Q. Well, this was an attachment to
24 the Howard Davis memo, so it would presumably
25 have the same date as the memo.

Page 246

1 A. Same date as the memo?

2 Q. Yes.

3 A. Okay.

4 Q. So November of 2010.

5 A. And who is this from?

6 Q. Well, actually, if you look

7 back at Exhibit 10 {sic}, the very bottom of

8 the memo, Mr. Davis says, "I recommend the

9 immediate revision of SOP number CS COMP 3.0

10 to include additional definitive criteria as

11 noted above." And then further down he says,

12 "The new draft SOP entitled 'Due Diligence

13 Procedures and Monitoring of Controlled

14 Substances Sales' is included for

15 consideration."

16 A. Okay.

17 Q. And that's what this document

18 is.

19 A. Oh, okay. So they were giving

20 us information on standard operating

21 procedure.

22 Q. And if it helps your review, my

23 questions relate to sections 4, 5, 7, 8 and 9

24 of the memo.

25 MR. TSAI: We've been going for

Page 247

1 about an hour. Is this a good time to

2 take a break since this is a long

3 document?

4 MR. KAWAMOTO: Well -- okay.

5 Well -- sure. Well, why don't I --

6 THE WITNESS: I'm willing to

7 go.

8 MR. KAWAMOTO: Okay. Well,

9 yeah -- well, why don't we keep going,

10 and if for whatever reason you want to

11 take a break, just let me know and I'm

12 happy to take a break.

13 THE WITNESS: Okay.

14 QUESTIONS BY MR. KAWAMOTO:

15 Q. So did you want to review some

16 more, or should I just ask you questions?

17 A. No, go ahead. I mean, I can

18 look at it to --

19 Q. Okay. So Section 4 is an

20 affidavit requirement.

21 A. Now, if I'm reading this right,

22 this is from the DEA, I believe you said?

23 Q. Well, no, that is something I

24 wanted to clarify with you.

25 A. Okay.

Page 248

1 Q. So Howard Davis is a -- I

2 believe he is a former DEA personnel.

3 A. Okay.

4 Q. And he was working as a

5 consultant for Mallinckrodt.

6 A. Oh, okay.

7 Q. I'm not -- I'm not positive

8 exactly what his status was.

9 A. Okay.

10 Q. But apparently Ms. Harper asked

11 him to review the S -- CS COMP 3.0 procedure,

12 and he prepared her this memo --

13 A. Okay.

14 Q. -- with these recommendations.

15 A. Oh, okay.

16 Q. So I guess my -- one thing I

17 wanted to ask you is that -- does that

18 change -- does that change any of your prior

19 testimony regarding Mr. Davis' views as he

20 expressed in his memo?

21 MR. TSAI: And I would like to

22 object for the record that that line

23 of questioning was -- didn't have that

24 clarification. And if we're just

25 clarifying the record, I think at this

Page 249

1 time when Exhibit 9 was written,

2 Howard Davis was not speaking on

3 behalf of the DEA or employed by the

4 DEA.

5 QUESTIONS BY MR. KAWAMOTO:

6 Q. So with that -- with that

7 clarification --

8 A. Okay.

9 Q. -- does that change your

10 opinion of any of the views he's expressing

11 in his memorandum?

12 A. Does it change my opinion?

13 What in particular did you want

14 to talk about? 4 or the whole thing or --

15 Q. Well, no, let's go back --

16 let's go back. I didn't realize that --

17 until I reviewed the transcript, I didn't

18 realize there was that confusion.

19 But going back to Exhibit 9 --

20 A. So this was written by someone

21 that I guess -- that we had -- that was a

22 former DEA employee that we had consulted

23 with to go over the -- our process --

24 Q. Yes.

25 A. -- and make recommendations?

Page 250

1 Q. That is my understanding.
2 Well, you, I believe -- based on this memo,
3 it appears you asked him to review the
4 program.
5 A. When you say "you" --
6 Q. I believe Karen Harper.
7 A. -- Karen Harper did.
8 Q. Yes.
9 A. Okay. So I just want to
10 establish that this is something that Karen
11 Harper had asked him to review and reported
12 it back to him. This is the first time I've
13 seen this document, so --
14 MR. TSAI: And again, I'll
15 object for the record to that line of
16 questioning and testimony, given the
17 misunderstanding that was just put on
18 the record.
19 QUESTIONS BY MR. KAWAMOTO:
20 Q. Well, okay. In that case, why
21 don't we turn to Exhibit 9. So can you pick
22 up Exhibit 9 again?
23 A. Okay.
24 Q. So this -- this is -- this is
25 the memo that Mr. Davis prepared for

Page 251

1 Ms. Harper?
2 A. Oh, okay.
3 Q. Okay?
4 A. Okay. So that makes it a
5 little more clear that he wasn't working for
6 the DEA.
7 Q. He was not working for the DEA,
8 though he was formerly employed by them and
9 presumably had some expertise.
10 A. Right. And he had -- Karen had
11 asked him to review our process.
12 Q. Yes.
13 A. Okay.
14 Q. And so when he says, "Federal
15 register notices published as early as 2007
16 state specifically that using formulas that
17 rely on percentages or averages over time has
18 been determined by the DEA to be
19 insufficient," would you agree with that
20 statement?
21 MR. TSAI: Object to the form.
22 THE WITNESS: Where are you at?
23 I'm sorry.
24 QUESTIONS BY MR. KAWAMOTO:
25 Q. The middle of the second

Page 252

1 paragraph.
2 A. Okay. Yes, I would agree with
3 that.
4 Q. Okay. And the statement that
5 "an order must not be processed and filled if
6 it is either suspicious or excessive," you
7 would agree with that statement?
8 A. Okay.
9 Q. Well, I'm sorry, so --
10 A. I'm just seeing now, he's
11 reviewing -- this is a review and -- of -- by
12 Howard Davis. And he's -- he's telling Karen
13 that right now, as the -- the current process
14 is being done is that we have time frame --
15 or we decided that we could allow an order
16 determined as peculiar to go ahead and ship
17 as long as we continued to do our due process
18 of following up on the order to make sure it
19 was not becoming a suspicious order -- not a
20 suspicious order.
21 So I think that's what he's
22 addressing.
23 Q. Okay.
24 A. Addressing here.
25 Then he goes on to address the

Page 253

1 other portion of what was in place at the
2 time, that we changed it from 2 X to 3 X.
3 Q. Uh-huh.
4 A. Okay? And he brought this up
5 as some concerns that he may have that we
6 might want to address.
7 Q. Okay. And so the statement he
8 has when "an order must not be processed and
9 filled if it is either suspicious or
10 excessive," do you agree with that statement?
11 Is he correct on that point?
12 A. I agree with what he is coming
13 back and telling us, that it should not be
14 shipped, okay?
15 And what I'm saying, as part of
16 our daily review prior to this, prior to
17 Howard Davis saying this, that we were going
18 ahead if the order was peculiar and we were
19 not able to completely vet the order -- and
20 what I mean by that is, as the sales
21 department or the salesmen or the marketing
22 person in a due fashion of time, that we
23 would go ahead and allow the order to ship,
24 and we would continue the process of
25 evaluating whether it should be moved to a

Page 254

1 suspicious order.
2 So he's coming back after
3 review and saying, "This is something that
4 you may want to not -- may not want to do."
5 Q. Okay. And do you agree with
6 his assessment, that that is something that
7 you don't want to do?
8 A. Well, at the time I don't -- I
9 didn't agree with it. I felt that we -- we
10 were doing our -- our job, and we had a
11 six-month or five-month history of working at
12 two months and not having an order that
13 became -- went from peculiar to suspicious,
14 and we felt it was okay based upon that to
15 move it to three times. All right? So we
16 felt that was okay. Karen approved.
17 And Howard came back, from what
18 I'm reading here, and saying that you may
19 want to change that. That's what I get out
20 of it.
21 Q. Well, actually, what he's
22 saying, if you just read the text, is, "An
23 order must not be processed and filled if it
24 is either suspicious or excessive."
25 So do you disagree with that

Page 255

1 statement?
2 Can an order be processed and
3 filled if it is suspicious or excessive?
4 A. Well, it shouldn't if it's
5 deemed suspicious.
6 Q. Okay. So if an order is -- if
7 an order is either suspicious or excessive,
8 it should not be processed and filled; is
9 that fair?
10 A. That's what he's saying, yes, I
11 agree with that.
12 Q. Then he goes on to say, "The
13 existing SOP excels to meet this requirement
14 through a specific evaluation process.
15 However, the numeric formula is problematic.
16 For example, should an occasion arise where
17 an order is three times over the historical
18 average for that customer and item, or in a
19 situation where the order meets but does not
20 exceed the three times criteria, it would
21 theoretically be filled through normal
22 processing without further question. In
23 doing so, in certain cases and as noted in
24 recent immediate suspensions of other
25 large-scale DEA registrants, which are all a

Page 256

1 matter of public record, Mallinckrodt would
2 be unnecessarily exposing itself to potential
3 liability."
4 A. Okay.
5 Q. Do you see that statement?
6 A. I do.
7 Q. Do you agree with that, sir?
8 MR. TSAI: Object to the form.
9 THE WITNESS: I guess all I can
10 say is that we felt that we could do
11 that. And Howard, who was a former
12 employee of the DEA, is saying as a
13 consultant that you may want to relook
14 at your -- and that's what Karen was
15 doing, was asking him to review what
16 we were doing and pointing out things
17 that he felt that we might be liable
18 for.
19 So in that case he's saying,
20 you may want to review your 2 X -- or
21 your 3 X program and change it to 2 X,
22 because the potential for orders going
23 through you might be liable for.
24 QUESTIONS BY MR. KAWAMOTO:
25 Q. And had How -- had you known

Page 257

1 that Howard had this concern, would you still
2 have supported a change from the 2 X to 3 X?
3 A. Well, I'm not sure when -- this
4 was done in October, I believe.
5 Q. Oh, it's November of 2010.
6 A. November of 2010. And I
7 believe we made that change prior to November
8 of 2010. Okay?
9 And to answer your question,
10 if -- if Howard pointed this out and Karen,
11 you know, agreed with him, we would change it
12 back to the 2 X.
13 Q. Well, putting Karen aside
14 because --
15 A. Right.
16 Q. -- you don't know what Karen
17 did, you know, after she received this memo,
18 correct?
19 A. Right.
20 Q. So just from the standpoint of
21 your support and your -- your support for the
22 change from 2 X to 3 X --
23 A. Right.
24 Q. -- if Mr. Davis had sent this
25 memo to you, would it have -- would it have

Page 258

1 affected your support for changing the
2 program from 2 X to 3 X?
3 MR. TSAI: Object to the form.
4 THE WITNESS: It probably would
5 have.
6 QUESTIONS BY MR. KAWAMOTO:
7 Q. Okay.
8 A. I thought I had answered that,
9 but maybe I'll make it clear.
10 Q. And when you say "it probably
11 would have," would it have made it less
12 likely that you would have supported the 2 X
13 to 3 X change?
14 MR. TSAI: Object to the form.
15 THE WITNESS: If I had known a
16 person who was familiar with the DEA
17 and we had hired to evaluate our
18 program, and he thought that it was --
19 it was potentially liable to change it
20 from 2 X to 3 X, I probably would not
21 have made that change.
22 QUESTIONS BY MR. KAWAMOTO:
23 Q. Okay. Now, flipping to the
24 next page that says, "Numeric formulas do not
25 identify circumstances that might be

Page 259

1 indicative of diversion."
2 Do you see that paragraph?
3 A. I'm sorry, say that again?
4 Which paragraph?
5 Q. Sure. It's the top paragraph
6 on page 2 of the memo.
7 A. Okay.
8 Q. It says, "Numeric formulas do
9 not identify circumstances."
10 Do you see that?
11 A. I do.
12 Q. Okay. And it identifies four
13 circumstances that are indicative of
14 diversion that wouldn't be captured by
15 numeric formula.
16 A. Okay.
17 Q. Do you agree with that
18 statement?
19 A. Well, what he's pointing out is
20 maybe things that we could add to our
21 program, and we were, of course, always ready
22 to take input from other resources.
23 I take it that's why we hired
24 Howard, to review our process and see if
25 there was anything that he felt that we could

Page 260

1 do to make it better.
2 Q. And what -- I mean,
3 specifically what he's doing here is he's
4 identifying various circumstances that aren't
5 captured by numeric formulas.
6 A. Okay.
7 Q. Would you agree that the four
8 circumstances he's identifying are not
9 captured by numeric formulas?
10 A. The four -- the four of them in
11 that paragraph?
12 Q. Yes, I believe so.
13 A. I'm not -- I'm not sure how we
14 would know or even ordering the same
15 controlled substance from multiple suppliers.
16 I'm not sure how we would know that.
17 Q. Okay. But you would agree,
18 though, that that is a factor that isn't
19 captured by a numeric formula --
20 A. That's true.
21 Q. -- putting aside the question?
22 Okay.
23 So with respect to these four
24 factors -- well, taking a step back.
25 You would agree that these four

Page 261

1 factors might be indicative of diversion; is
2 that fair?
3 MR. TSAI: Object to the form.
4 THE WITNESS: It's possible,
5 yes.
6 QUESTIONS BY MR. KAWAMOTO:
7 Q. Okay. And you would also agree
8 that these four factors are not captured by
9 numeric formula?
10 A. I think that's what he's
11 pointing out, yes.
12 Q. And you would agree with him on
13 that?
14 A. Yes.
15 Q. Okay. And then these four
16 factors were also the same ones indicated by
17 the DEA in September of 2006. This is
18 Exhibit 2.
19 A. Okay.
20 Q. Right. I just wanted to make
21 sure your testimony on that hasn't changed.
22 A. No, it hasn't changed.
23 Q. Okay. And then going to the
24 paragraph underneath the paragraph regarding
25 numeric formulas where it says, "The DEA

Page 262

1 registrant population as a whole is now
 2 required to consider the totality of the
 3 circumstances when evaluating an order prior
 4 to it being filled."
 5 Do you see that statement?
 6 A. I do.
 7 Q. And you would agree with that,
 8 correct?
 9 A. I agree.
 10 Q. Okay. And then going down to
 11 the nine bullet points that Mr. Davis
 12 identifies as being important information to
 13 gather from customers, you would still agree
 14 that that is important information?
 15 MR. TSAI: Object to the form.
 16 THE WITNESS: I believe this --
 17 yes, they would be important factors.
 18 QUESTIONS BY MR. KAWAMOTO:
 19 Q. Okay. So putting that document
 20 aside and turning now to Exhibit 10. So --
 21 A. I just was reading this last
 22 one.
 23 Q. Go ahead.
 24 A. I wanted to see what he
 25 recommended.

Page 263

1 Okay.
 2 Q. Now, turning to --
 3 A. This is the draft that he
 4 prepared?
 5 Q. Yes, this is the draft that he
 6 prepared. This, I believe, is Exhibit 10.
 7 A. Okay.
 8 Q. So do you see on page -- or
 9 Section 4 of this draft it says, "Affidavit"?
 10 A. Okay.
 11 Q. Okay.
 12 A. Okay.
 13 Q. Okay. So this -- this is --
 14 Howard is proposing an affidavit requirement,
 15 and the affidavit would verify that the
 16 customer is not an online pharmacy and has
 17 never conducted business as an Internet
 18 pharmacy and is otherwise aware of their
 19 corresponding responsibility for dispensing
 20 controlled substances legitimately.
 21 Do you see that?
 22 A. I do.
 23 Q. Do you think that this
 24 requirement makes sense as part of a
 25 suspicious order monitoring program?

Page 264

1 A. I do.
 2 Q. Okay. Do you know if this
 3 requirement was ever put in place?
 4 A. I believe it was.
 5 Q. Okay.
 6 A. I believe it was part of the
 7 CDIG checklist that was sent out to the
 8 customers.
 9 Q. Okay. Section 5, which is
 10 background documentation. And these are
 11 documents by customer type, asking the
 12 customer specific questions about their
 13 businesses and their licenses.
 14 And can you review the various
 15 questions?
 16 A. Okay.
 17 Q. Okay. Do you agree that it
 18 makes sense to ask customers these types of
 19 questions?
 20 MR. TSAI: Object to the form.
 21 QUESTIONS BY MR. KAWAMOTO:
 22 Q. Well, let me rephrase that.
 23 Do you agree that customers
 24 should be asked the following questions that
 25 he identifies?

Page 265

1 MR. TSAI: Object to the form.
 2 THE WITNESS: I guess I agree
 3 that these are things that should
 4 be -- again, Howard, I guess, was
 5 making recommendations, and I believe
 6 that I shouldn't -- I shouldn't speak
 7 out of turn because I was in customer
 8 service. So this would have been part
 9 of the CDIG process, so -- but I do
 10 agree these are things that we could
 11 possibly ask.
 12 QUESTIONS BY MR. KAWAMOTO:
 13 Q. Okay. And, well, not only
 14 could you possibly ask for them, but you
 15 would agree that it would be a good idea to
 16 ask these questions?
 17 MR. TSAI: Object to the form.
 18 THE WITNESS: Like I said, it
 19 would be a good idea.
 20 QUESTIONS BY MR. KAWAMOTO:
 21 Q. Okay. Then turning to
 22 Section 7, it says "Memos."
 23 A. Okay.
 24 Q. Okay. Now, do you agree that
 25 this would be a good modification to the

<p style="text-align: right;">Page 266</p> <p>1 suspicious order monitoring program?</p> <p>2 A. I agree that it would enhance</p> <p>3 it, yes.</p> <p>4 Q. Okay. Do you know if this was</p> <p>5 done?</p> <p>6 A. I don't know.</p> <p>7 Q. Okay. Then Section 8 is an</p> <p>8 on-site inspection report. And it says, "If</p> <p>9 a customer is flagged suspicious based on</p> <p>10 their ordering habits or their due diligence</p> <p>11 documents, then the compliance department may</p> <p>12 require that an on-site inspection be</p> <p>13 conducted by a third-party, experienced,</p> <p>14 trained investigator."</p> <p>15 Do you see that section?</p> <p>16 A. Uh-huh, I do.</p> <p>17 Q. Do you think that requirement</p> <p>18 makes sense as an addition to the suspicious</p> <p>19 order monitoring program?</p> <p>20 A. You're asking me as a customer</p> <p>21 service manager if I feel that this is --</p> <p>22 would be important?</p> <p>23 Q. Yes. And as someone that was</p> <p>24 involved in setting up the SOM program, a</p> <p>25 member of the SOM team.</p>	<p style="text-align: right;">Page 268</p> <p>1 location, review documents, inspect the</p> <p>2 customer's facility, observe the customer's</p> <p>3 dispensing and/or examination practices,</p> <p>4 request additional information from the</p> <p>5 customer and complete an inspection report."</p> <p>6 Do you agree that that would</p> <p>7 have been factors that a third-party</p> <p>8 investigator should have looked at?</p> <p>9 MR. TSAI: Object to the form.</p> <p>10 THE WITNESS: It's something</p> <p>11 that could have been done, yes.</p> <p>12 QUESTIONS BY MR. KAWAMOTO:</p> <p>13 Q. Well, I mean -- well, strike</p> <p>14 that.</p> <p>15 Not only could it have been</p> <p>16 done, but it would have enhanced the program,</p> <p>17 would it not?</p> <p>18 A. It would have enhanced any</p> <p>19 program.</p> <p>20 Q. Okay. Do you know if this was</p> <p>21 actually done?</p> <p>22 A. I don't know.</p> <p>23 Q. Okay. Then Section 9 is</p> <p>24 parameters used in defining orders of</p> <p>25 interest.</p>
<p style="text-align: right;">Page 267</p> <p>1 A. Well, this is -- this is</p> <p>2 enhancements to the SMO {sic} team, and I</p> <p>3 believe -- well, a form of this was done, as</p> <p>4 I explained earlier, where Karen Harper and</p> <p>5 the team were going ahead and making audits</p> <p>6 on -- with customers. So that's as far as I</p> <p>7 know what was implemented as of the time that</p> <p>8 I was there.</p> <p>9 Q. Do you know if Karen -- I</p> <p>10 believe you previously testified that the</p> <p>11 audits were conducted by Karen Harper and --</p> <p>12 A. A team of other individuals.</p> <p>13 I'm not sure who was all on the team. I know</p> <p>14 one of our lawyers were, and there -- I'm not</p> <p>15 sure if they went ahead and got an</p> <p>16 investigator or not.</p> <p>17 Q. Okay. So you don't know if</p> <p>18 they used a third-party, experienced, trained</p> <p>19 investigator?</p> <p>20 A. I don't. I don't.</p> <p>21 Q. Do you think it would have been</p> <p>22 a good idea to do so?</p> <p>23 A. It wouldn't have hurt.</p> <p>24 Q. Okay. It also says, "The</p> <p>25 investigator will visit the customer</p>	<p style="text-align: right;">Page 269</p> <p>1 Do you see that?</p> <p>2 A. I do.</p> <p>3 Q. Okay. So orders of unusual</p> <p>4 size would be a parameter that should be used</p> <p>5 in defining an order of interest; is that</p> <p>6 correct?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. What about an order</p> <p>9 deviating substantially from a normal</p> <p>10 pattern?</p> <p>11 A. Yes.</p> <p>12 Q. What about orders of unusual</p> <p>13 frequency?</p> <p>14 A. Yes.</p> <p>15 Q. What about will call orders,</p> <p>16 meaning requested to be picked up?</p> <p>17 A. We didn't -- we didn't allow</p> <p>18 will call orders that I remember in the</p> <p>19 dosage group.</p> <p>20 Q. Okay. What about orders to be</p> <p>21 delivered -- well, so strike that.</p> <p>22 So will call orders then should</p> <p>23 not have been permitted?</p> <p>24 A. I want to say that it wasn't,</p> <p>25 but I can't verify -- say for sure that that</p>

Page 270

1 was true. I don't --
2 Q. I'm sorry, go ahead.
3 A. Go ahead.
4 Q. But in your opinion, will call
5 orders should not have been permitted?
6 A. I would -- I would say that
7 that's true.
8 Q. Okay. Orders to be delivered
9 to a different location, that should also not
10 have been permitted?
11 A. I agree.
12 Q. Okay. Cash orders should not
13 have been permitted?
14 A. I don't -- yes, I agree.
15 Q. And orders placed out of a
16 scope of the customer's field of practice,
17 that should not have been permitted?
18 MR. TSAI: Objection to the
19 form.
20 THE WITNESS: I'm not sure if I
21 understand what he's saying here, "out
22 of the scope of the customer's field
23 of practice." I'm not sure I know
24 what that is.
25

Page 271

1 QUESTIONS BY MR. KAWAMOTO:
2 Q. Okay. Could he be referencing,
3 for example, if you have a customer of a
4 distributor that is, you know, in a certain
5 practice area and they are prescribing drugs
6 that are generally not used by that practice
7 area?
8 MR. TSAI: Object to the form.
9 THE WITNESS: I'm not really
10 sure what he's -- what he's saying
11 here. I'm not sure if that's -- what
12 you're saying is right or not.
13 QUESTIONS BY MR. KAWAMOTO:
14 Q. Okay. And then the next bullet
15 point is, "Orders placed for more than one
16 controlled substance that are known to be
17 taken together, drug combinations, outside of
18 normal prescribing and patient treatment
19 practices. Such an example may be narcotics
20 with benzodiazapines, Soma and sleep aids
21 known as narcotic cocktails."
22 So do you believe that these
23 types of orders should not have -- that these
24 types of orders should not have been placed?
25 MR. TSAI: Object to the form.

Page 272

1 THE WITNESS: I would say that
2 that would be an enhancement, yes.
3 QUESTIONS BY MR. KAWAMOTO:
4 Q. Okay. And then actually if you
5 look -- do you see number 1 below Section 9?
6 A. I do.
7 Q. It says, "A physician or
8 veterinarian orders certain controlled
9 substances that are not consistent with a
10 type of practice identified by the
11 practitioner's licenses."
12 So that would, I imagine, be an
13 example of an order placed out of a scope of
14 a customer's field of practice?
15 A. Yes, I would agree with that.
16 Q. Okay. And so that is something
17 that should have been considered in
18 determining whether or not to fill an order;
19 is that correct?
20 MR. TSAI: Object to the form.
21 THE WITNESS: I -- I would
22 agree with that other -- other than we
23 weren't filling orders from physicians
24 or veterinarians. I'm not sure where
25 this is coming from.

Page 273

1 QUESTIONS BY MR. KAWAMOTO:
2 Q. Okay. So that's all I have on
3 that exhibit.
4 MR. KAWAMOTO: Rocky, did you
5 want to take a break now?
6 MR. TSAI: Let's take a break.
7 MR. KAWAMOTO: Okay.
8 VIDEOGRAPHER: We're going off
9 the record at 4:11 p.m.
10 (Off the record at 4:11 p.m.)
11 VIDEOGRAPHER: We are back on
12 the record at 4:31 p.m.
13 QUESTIONS BY MR. KAWAMOTO:
14 Q. Okay. So, Mr. Rausch, the last
15 topic I want to cover with you is the
16 clearing of suspicious orders. And what I
17 mean by that is you had previously indicated
18 that you would receive these reports, and
19 then you would contact various people
20 regarding the justification.
21 A. Right.
22 Q. And so just so, you know, both
23 of us are on the same page as to my
24 questions --
25 A. Yes.

Page 274

1 Q. -- I want to explore that
 2 process.
 3 A. Okay.
 4 Q. Now, would you agree with the
 5 statement that it's important to formally
 6 document the investigation of a peculiar
 7 order, including the hows and whys of the
 8 logic that was used to determine that the
 9 order was either appropriate or inappropriate
 10 to ship?
 11 A. I can tell you what we did.
 12 Q. Okay. What did you do then?
 13 A. Okay. So we would get the
 14 reports, and as I had talked earlier, we had
 15 several orders on that report that were
 16 flagged as peculiar. And I would go down the
 17 line, as I had mentioned earlier, and look at
 18 why it was kicking out. There was different
 19 flags, reasons, that would be checked on why
 20 the order would be flagged. So I would take
 21 a look at that.
 22 And then I would take a look at
 23 reports that I had to my disposal and see if
 24 there was anything else that I could see
 25 that may be why the order had been flagged

Page 275

1 that would be okay. Okay?
 2 If I could not determine
 3 through what I had available to me, then I
 4 would go to the CSR, then to the business
 5 manager and then to the sales force. And I
 6 would send out e-mails to the folks, if I
 7 needed to, and document that and attach that
 8 to the report. Okay?
 9 And then this was filed in the
 10 file folder for the month. I believe it's
 11 for the month.
 12 Q. And the documentation of the
 13 order with respect to the information you
 14 received from either the CSR or the business
 15 manager or the sales force, that consisted of
 16 whatever they e-mailed in response to you?
 17 A. Yes.
 18 Q. So there was no formal,
 19 separate report or memo that was prepared?
 20 A. No. No.
 21 (Mallinckrodt-Rausch Exhibit 11
 22 marked for identification.)
 23 **QUESTIONS BY MR. KAWAMOTO:**
 24 Q. Okay. So I'd like to mark this
 25 as Exhibit 11, and it is -- let's see. It

Page 276

1 bears the Bates number MNK-T1_307119.
 2 And this is an e-mail exchange
 3 between you and, I believe, people in sales
 4 regarding a suspicious order and the business
 5 justification for it; is that fair?
 6 A. Yes. Let me read it here.
 7 Q. Okay.
 8 A. Okay. This was a bulk
 9 customer.
 10 Q. Okay. And do you recall
 11 sending or receiving these e-mails?
 12 A. I do.
 13 Q. Okay. So the top e-mail, it's
 14 to Bill Ratliff, who is director of security.
 15 A. Right.
 16 Q. And it says, "See the
 17 information below. Sovereign is an
 18 established customer that we have dealt with
 19 for years. They are a contract manufacturer
 20 that may have gotten some new business. Let
 21 me know if we need to do anything else."
 22 So this e-mail is the -- is a
 23 complete report with respect to the
 24 justification for shipping this order; is
 25 that fair?

Page 277

1 A. I'm not sure if it's the
 2 complete report. I don't see a response from
 3 Bill.
 4 Q. Okay.
 5 A. So I'm sure there was, you
 6 know, continued e-mails on what he -- if he
 7 gave his approval or not.
 8 Q. Okay. Now, it says they're a
 9 contract manufacturer that may have gotten
 10 some new business.
 11 A. That's -- okay.
 12 Q. Do you see the "may"?
 13 A. Yes.
 14 Q. So that indicates that you
 15 weren't sure whether they had gotten new
 16 business. You thought they may have?
 17 A. That's what Tom Palmer is
 18 saying, yes.
 19 Q. Okay. So do you know if Tom
 20 took any steps to verify that they in fact
 21 had new business?
 22 A. I cannot tell that from what he
 23 put in this e-mail.
 24 Q. Okay. Did you take any steps
 25 to verify that they in fact had gotten some

Page 278

1 new business?

2 A. You know, he mentions here that
3 both Marilyn and Camille are aware of the
4 situation. If he learns any more, he would
5 let us know.

6 So, you know, without all the
7 communication that was involved in this
8 e-mail, I can't really answer that question
9 because I don't see a response from Bill here
10 and any continued communication what
11 occurred. So to say if this is complete, I
12 would say, no, it is not complete.

13 Q. Okay. So do you recall taking
14 any additional steps to verify this
15 information?

16 A. I don't remember. I don't
17 remember, to answer your question.

18 Q. Okay. You indicate, you say,
19 "Bill, let me know if we need to do anything
20 else."

21 A. Right.

22 Q. So if Bill were to say no, then
23 I assume this would be the complete record;
24 is that correct?

25 A. "No" meaning that we should not

Page 279

1 ship it or we would --

2 Q. No. If Bill says, no, we don't
3 need to do anything else, if Bill approves
4 this for shipment, then this is a complete
5 record?

6 A. I believe so, yes.

7 Q. Okay. And you don't recall
8 whether Bill said yes or not?

9 A. I don't see a response here, so
10 I don't remember, no.

11 Q. Okay.

12 A. This was, you know, not --

13 Q. Was it Bill --

14 A. Ten years ago.

15 Q. Was it Bill's general practice
16 to request for more information, or did he
17 generally just approve these?

18 A. No, he -- he would -- he would
19 do -- he would look into it, yes.

20 (Mallinckrodt-Rausch Exhibit 12
21 marked for identification.)

22 QUESTIONS BY MR. KAWAMOTO:

23 Q. Okay. So this is another
24 exhibit. I'm marking it as Exhibit 12, and
25 it bears the Bates number 266788.

Page 280

1 A. Okay.

2 Q. Okay. Do you recall sending
3 and receiving this e-mail?

4 A. I don't recall, but I -- I'm
5 sure -- I'm sure I sent it.

6 Q. Okay. And this is an e-mail
7 from you to Kate and Kate to you --

8 A. Correct.

9 Q. -- regarding an oxycodone
10 order.

11 A. Yes.

12 Q. And, you know, you're flagging
13 an increase in the order.

14 A. Correct.

15 Q. And Kate's response is, "Jim,
16 we are the secondary with CVS Caremark and
17 this product. There is only one other
18 supplier in the market, so my guess is that
19 they're not able to get it from them and have
20 ordered from us."

21 A. Okay.

22 Q. "I don't think it is too big of
23 a reason to be alarmed. Thanks, Kate."

24 A. Okay. Kate was the business
25 person for the product.

Page 281

1 Q. Okay. And so she's saying it's
2 her guess --

3 A. Right.

4 Q. -- that that's why this is.

5 A. Right.

6 Q. Do you know if she did anything
7 to verify her guess?

8 A. I would have probably reached
9 out to the salesperson.

10 Q. Okay. And who is the
11 salesperson?

12 A. I don't remember who the
13 salesperson was for Caremark at this -- off
14 the top of my head, I don't remember who it
15 is.

16 Q. But you would have taken steps
17 to verify Kate's guess?

18 A. Yeah, my -- my guess is not
19 good enough for allowing this order to go
20 out, I don't believe.

21 Q. Okay. So this should have been
22 verified?

23 A. Yes.

24 Q. And presumably that
25 verification would have been attached to the

Page 282

1 suspicious order report?
2 A. I would have hoped so, yes.
3 Q. Okay. And it was your practice
4 to attach any verification?
5 A. Yes.
6 Q. Okay. If this wasn't verified
7 and this went out just based on Kate's guess,
8 that would -- in your view, that would be a
9 problem?
10 A. It could be a problem, yes.
11 (Mallinckrodt-Rausch Exhibit 13
12 marked for identification.)
13 QUESTIONS BY MR. KAWAMOTO:
14 Q. Okay. So this is now
15 Exhibit 13, and it's being tagged as MN --
16 I'm sorry, bears the Bates number
17 MNK-T1_266996.
18 A. Okay.
19 Q. Okay. So this is another
20 e-mail chain between you and Kate
21 Muhlenkamp --
22 A. All right.
23 Q. -- regarding a suspicious
24 order. Or I'm sorry, regarding a peculiar
25 order. And --

Page 283

1 A. Okay.
2 Q. -- what she says to you is,
3 "Jim, I followed up with Steve Becker."
4 Would Steve Becker have been
5 the business person?
6 A. He would have been the
7 salesperson, I believe.
8 Q. The salesperson? Okay.
9 A. Uh-huh.
10 Q. "He noted that Henry Schein had
11 recently made changes to their internal
12 structure and are now servicing additional
13 third-party contracts, chargebacks, which may
14 be driving their new demand. He was not
15 surprised that they had started ordering.
16 Hope this helps."
17 Do you know if any steps were
18 taken to verify that the internal structure
19 was in fact driving the new demand?
20 A. I don't remember.
21 Q. Okay. Should additional steps
22 have been taken to verify that?
23 A. It could have been warranted,
24 yes.
25 Q. Okay. And if -- if, in fact,

Page 284

1 it was verified, it would have been
2 documented as an e-mail attached to the
3 suspicious order report, correct?
4 A. It could have been, yes.
5 Q. Okay.
6 A. Should have been.
7 Q. Now, the suspicious order
8 report, I believe, is that on Bates
9 number 266995?
10 A. Is it what? I'm sorry?
11 Q. I'm looking at Bates
12 number 266995. It's a list of orders.
13 A. Okay.
14 Q. Is that the suspicious order
15 report?
16 A. Yes.
17 Q. Okay. And then behind that, on
18 page 266997, that's the actual orders; is
19 that correct?
20 A. Correct.
21 Q. Okay. So, you know, the
22 complete --
23 A. Is there an order number here?
24 Q. Sure.
25 A. I'm just seeing if it had the

Page 285

1 order number on there.
2 I'm seeing whether it
3 referenced anything that is quoted in the
4 e-mail. I'm trying to see if there's
5 anything about 456 bottles on here. I don't
6 see that.
7 And this is dated -- this is
8 dated April 26th, and this report's dated
9 4/23.
10 I'm trying to see if there's
11 something that's -- identifies on this report
12 this -- what we were e-mailing about. I see
13 Henry Schein, but I don't see the order
14 quantity that was talked about.
15 It says 456, and I don't see
16 that on -- on what's attached here.
17 So anyway -- okay. So I'm
18 assuming that what's attached here is
19 referencing an order that the e-mail is
20 talking to.
21 Q. Okay. So this -- this e-mail
22 then would have been the just -- the complete
23 justification for shipping this order?
24 A. I believe so.
25 Q. Okay. And so no steps were

Page 286

1 taken then to verify that in fact the
2 internal structure was what was driving their
3 demand; is that correct?
4 A. I imagine this was the end of
5 it, yes.
6 Q. Okay. And so this -- okay.
7 Strike that.
8 (Mallinckrodt-Rausch Exhibit 14
9 marked for identification.)
10 QUESTIONS BY MR. KAWAMOTO:
11 Q. So I'd like to mark this as
12 Exhibit 14, and it bears a Bates number
13 MNK-T1_266735.
14 A. Okay.
15 Q. Okay. Now, this is an e-mail
16 exchange between you and Penny Myers.
17 Who is Penny Myers?
18 A. She was a business manager.
19 Q. Okay. And this is -- do you
20 recall receiving -- well, do you recall
21 sending and receiving these e-mails?
22 A. I don't recall it, but I -- I
23 wrote it, so, yes.
24 Q. Okay. And you were -- you were
25 asking her about a suspicious order from

Page 287

1 HD Smith -- or, I'm sorry, a peculiar order
2 for HD Smith, and Penny indicates to you that
3 the order is due to increased compliance and
4 new pharmacies being added.
5 And then you ask her, "What is
6 increased compliance?" and the answer she
7 gives you is above.
8 Is this the complete record for
9 the justification of this order?
10 A. I don't remember.
11 Q. Okay. Now, increased
12 compliance. Now, Penny -- well, strike that.
13 You asked her what increased
14 compliance is, and Penny responds, "When we
15 offer a price, we asked for the estimated
16 quantity that they will purchase. If they
17 don't purchase close to the amount they
18 estimated, we encourage them to do that or
19 their price may not remain the same or their
20 VIP provision may change."
21 Do you see that?
22 A. I do.
23 Q. And what do you understand her
24 to be saying with that?
25 A. What I'm understanding her to

Page 288

1 say, okay, and from what I read here is she's
2 saying, okay, based upon estimates from the
3 customers of how much they'll be purchasing,
4 we offered them a price. Okay?
5 If they don't purchase close to
6 that amount, we -- the amount they estimate,
7 we encourage them to do that or their price
8 may be adjusted. Okay?
9 So based upon their volume,
10 they -- they would -- you can buy at
11 different tiers, is what I'm assuming this is
12 saying.
13 Q. So in other words, if they
14 don't purchase close to their estimated
15 quantity, there's a financial, you know,
16 penalty or consequence that gets attached; is
17 that fair?
18 A. We're -- from what I read, it
19 sounds that -- when you say "penalty," no,
20 they're telling us that, okay, based upon the
21 amount that they estimated to be buying from,
22 we quote them a price. Okay? If they don't
23 buy that, then we're probably going to have
24 to increase the price.
25 Q. Okay.

Page 289

1 A. You called it a penalty. We
2 call it -- I wouldn't call it a penalty.
3 Q. But it would be fair to say
4 they are getting a less favorable price?
5 A. Correct.
6 Q. So they have a financial
7 incentive from Mallinckrodt to increase their
8 order; is that fair?
9 A. Correct.
10 Q. Okay. So in essence, in the
11 context of this e-mail, there is a financial
12 incentive from Mallinckrodt to have this
13 seller essentially put in a peculiar order?
14 MR. TSAI: Object to the form.
15 THE WITNESS: No, I wouldn't
16 say a peculiar order.
17 QUESTIONS BY MR. KAWAMOTO:
18 Q. Well, this order was flagged in
19 the system as a peculiar order, was it not?
20 A. It was. Okay. So what
21 they're -- what it is is that, okay, the
22 order is more than what they've ordered in
23 the past. The system flagged it. The
24 business manager reached out to the sales --
25 to the customer -- or came back to Penny and

Page 290

1 said, "This is the reason why the orders have
2 increased, because we've given them a better
3 price if they buy more." So that was
4 justification for the order.
5 Q. Okay. And you don't know if
6 they actually had an increase in demand,
7 right? Well, strike that.
8 A. I don't know that.
9 Q. There's no indication that they
10 had an increase in demand. They might well
11 be purchasing this additional amount because
12 they don't want to have to pay the increased
13 price?
14 A. I don't know. That's
15 speculation. I can't answer that.
16 Q. But there's nothing in this
17 e-mail that indicates that they are --
18 A. One way or the other.
19 Q. Yes.
20 Okay. So they are -- according
21 to this e-mail, the reason they're asking for
22 significant -- for significantly more than
23 they previously asked for is because they
24 don't want to have to pay a less favorable
25 price; is that fair?

Page 291

1 A. That's correct.
2 But that was -- that was the
3 reason why it hit the peculiar order report,
4 and this was the responses back of why.
5 (Mallinckrodt-Rausch Exhibit 15
6 marked for identification.)
7 QUESTIONS BY MR. KAWAMOTO:
8 Q. I'm going to mark this document
9 as Exhibit 15, and this is MNK-T1_266730.
10 Actually, I'm sorry, I just had
11 one more question on Exhibit 14, the
12 compliance e-mail.
13 Could you turn to that again?
14 A. I'm sorry, which one?
15 Q. The prior one.
16 A. This one.
17 Q. So I think it's Exhibit 14.
18 A. Exhibit 14? Okay.
19 Q. So the increased compliance
20 justification, that would have been
21 sufficient to justify shipping the order?
22 A. Yes.
23 Q. Okay. Thank you.
24 So now we're on Exhibit 15?
25 A. Yes.

Page 292

1 Okay.
2 Q. Okay. So this is an e-mail
3 between you and Lisa Lundergan.
4 Who is Lisa Lundergan?
5 A. I believe she was a business
6 manager.
7 Q. Okay. And do you recall
8 sending or receiving these e-mails?
9 A. I don't recall it, but I see
10 that I did.
11 Q. Okay. And then this -- this
12 involves an order for 44,208 bottles of
13 morphine oral --
14 A. Okay.
15 Q. -- which was three times more
16 than they had ever placed before, and hence
17 it tripped the algorithm.
18 A. Correct.
19 Q. And Lisa's response to your
20 question as to why they are placing such an
21 order is, "Yes, we are offering them the
22 remainder of our inventory for morphine oral
23 since it was being discontinued. Thank you
24 for checking."
25 A. Okay.

Page 293

1 Q. Would that justification have
2 been sufficient for you to ship this order?
3 A. Yes.
4 Q. Okay. Is it a cause for a
5 concern that -- well, strike that.
6 (Mallinckrodt-Rausch Exhibit 16
7 marked for identification.)
8 QUESTIONS BY MR. KAWAMOTO:
9 Q. Okay. So this is Exhibit 16
10 now. It bears the Bates number
11 MNK-T1_298447.
12 A. Okay.
13 Q. So this says, "Cardinal placed
14 a large order for" -- 851501, I believe
15 that's the order number -- "for
16 12,720 bottles" -- I'm sorry, let me take a
17 step back.
18 So this is an e-mail between
19 you and Kate Muhlenkamp again?
20 A. Correct.
21 Q. Do you recall receiving or
22 sending these e-mails?
23 A. No.
24 Q. Okay. Do you have any reason
25 to doubt that you did send or receive them?

Page 294

1 A. No.
2 Q. Okay. And so the e-mail -- the
3 e-mail from you to Kate is that Cardinal has
4 placed an order for 12,720 bottles, and their
5 average has been 3,227.
6 A. Okay.
7 Q. And you wanted to know why
8 they're increasing their inventory for these
9 two products.
10 A. Okay.
11 Q. And her response is that she
12 has been working with Cardinal to increase
13 their inventories.
14 A. Correct.
15 Q. Okay. Would that have been a
16 sufficient justification to ship this order?
17 A. Yes.
18 Q. Okay. Do you know why Kate was
19 working with Cardinal to increase their
20 inventories?
21 A. I don't remember, no.
22 Q. Okay. Was it -- was it a
23 concern to Mallinckrodt if a distributor was
24 accumulating an excessively large inventory of
25 opioid products?

Page 295

1 MR. TSAI: Object to the form.
2 THE WITNESS: I think what Kate
3 was doing here was that Cardinal --
4 well, I shouldn't -- I shouldn't
5 speculate. I don't know what -- how
6 to answer that.
7 It would have been a concern,
8 well, our business manager felt that
9 it was appropriate that we reached out
10 to them and asked them for reasons
11 that I can't answer right now, to go
12 ahead -- if they would go ahead and
13 increase their inventories.
14 QUESTIONS BY MR. KAWAMOTO:
15 Q. From a diversion control
16 standpoint, though, is it a concern when a
17 distributor starts accumulating a very large
18 inventory of controlled substances?
19 MS. YOCUM: Objection to form.
20 THE WITNESS: I think we were
21 reaching out to them, so it was okay
22 with us if they went ahead -- if we
23 could ship this to them.
24 So, again, we are not the --
25 the sole party in this stream of

Page 296

1 diversion and that as you referred to
2 in -- before, you know, the
3 distributors had their own programs in
4 place for diversion.
5 As you can see from the e-mail,
6 we were -- we were doing our part as
7 far as checking why the order was
8 placed, and in my view, we did our due
9 diligence of reaching out to the
10 business manager. The business
11 manager had asked if -- on our behalf
12 if they would take a larger increase
13 of this product, and as far as I was
14 concerned, that was okay for releasing
15 the order.
16 QUESTIONS BY MR. KAWAMOTO:
17 Q. Do you know if Karen Harper
18 signed off on the desire to have Cardinal
19 increase their inventories?
20 A. I don't know that, no.
21 Q. Would this have been a decision
22 she should have been involved in?
23 A. I'm not sure if she should be
24 or not.
25 What's your -- what's your --

Page 297

1 well, okay. Go ahead.
2 Q. Well, would -- would you agree
3 that it is a concern --
4 A. I can't -- I can't answer what
5 Kate's thinking was on this or what was going
6 on behind the scenes as far as us asking them
7 to increase their inventories. Maybe they
8 were keeping lower-than-expected inventories.
9 Maybe -- I don't know. I can't answer for
10 what reasons Kate Muhlenkamp had for asking
11 for this.
12 Q. Well, I'm not asking for -- I'm
13 not asking for your speculation as to what
14 Kate was thinking.
15 A. Okay, but you're -- okay, go
16 ahead.
17 Q. What I am asking is, from the
18 standpoint of diversion control, is it a
19 concern to have distributors accumulating
20 large inventories of controlled substances?
21 A. If they have -- in my
22 viewpoint, if they have the controls in
23 place, it would not -- it would not be a
24 problem.
25 Q. And by "controls in place,"

Page 298

1 what do you mean by that?

2 A. Suspicious order monitoring

3 program.

4 (Mallinckrodt-Rausch Exhibit 17

5 marked for identification.)

6 QUESTIONS BY MR. KAWAMOTO:

7 Q. So I'd like to mark this as

8 Exhibit 17.

9 A. Okay.

10 Q. So here's an e-mail from Cheryl

11 Nelson to Marc Montgomery and Kate

12 Muhlenkamp, and you're cc'd on it.

13 A. Correct.

14 Q. Do you recall receiving this?

15 A. No, but I see that I'm cc'd on

16 it, so I would have received it, I guess.

17 Q. Okay. And so Cheryl is asking

18 Kate and Marc about a shipment that has

19 triggered the -- the suspicious order

20 algorithm, or the peculiar order algorithm;

21 is that correct?

22 A. I don't know if it triggered

23 it, but from what I recall -- I don't know

24 where she's getting "we have experienced

25 considerable diversion tampering issues." I

Page 299

1 don't remember that, if that was the case

2 anymore.

3 But what they're saying here

4 is, there was a shortage, if I remember

5 right, of this product, and customers were

6 only allowed so much a month based upon

7 history, sales history, to them.

8 And from what I see here,

9 Cheryl was reaching out and asking who

10 were -- Kate and Marc, who were doing the

11 allocations, if it would be okay to ship them

12 material.

13 Q. Okay. And so Mark says that

14 it's okay, and Kate says that it's okay; is

15 that correct?

16 A. Okay. Yes.

17 Q. So would this order have been

18 shipped?

19 A. Yes, I would assume it would

20 be. I don't -- Kate -- yes, I would assume

21 it was, because it's not kicking out on the

22 suspicious order program.

23 Q. Okay. So no one did any

24 follow-up regarding what the considerable

25 diversion or tampering issues were with

Page 300

1 regard to this customer at NC?

2 A. I don't remember.

3 Q. Okay.

4 A. Again, I don't think it was

5 anything that kicked out as far as being on

6 a -- on the peculiar order report. I think

7 Cheryl was just reaching out and saying that

8 they had already reached the quantity of what

9 they could buy, and they were asking if they

10 could buy more or whatever. That's what I --

11 what I read out of this.

12 And she reached out to -- to

13 Marc Montgomery, who was the director of

14 marketing.

15 Q. So this -- and this would have

16 been sufficient to allow this shipment to go

17 through then?

18 A. Yes.

19 MR. KAWAMOTO: Okay. So why

20 don't we take a very short,

21 five-minute break, and I should be

22 close to wrapping up.

23 VIDEOGRAPHER: We're going off

24 the record at 5:06 p.m.

25 (Off the record at 5:06 p.m.)

Page 301

1 VIDEOGRAPHER: We are back on

2 the record at 5:14 p.m.

3 MR. KAWAMOTO: Okay.

4 Mr. Rausch, thank you for your time.

5 I have no further questions.

6 THE WITNESS: Okay. Thank you.

7 MR. TSAI: So just to clarify,

8 in case of redirect, I think I

9 probably have five minutes.

10 Do you want to do that now, or

11 should we do Tennessee first?

12 MS. CONWAY: I think

13 timing-wise, it should be fine for

14 her.

15 MR. TSAI: Okay.

16 VIDEOGRAPHER: We are going off

17 the record at 5:14 p.m.

18 (Off the record at 5:14 p.m.)

19 VIDEOGRAPHER: We are back on

20 the record at 5:15 p.m.

21 CROSS-EXAMINATION

22 QUESTIONS BY MS. HERZFELD:

23 Q. Mr. Rausch, how are you doing

24 this evening?

25 A. Getting tired.

Page 302

1 Q. Getting tired.
2 Okay. You're okay to go for
3 another hour or so?
4 A. Is that what it's going to be?
5 Q. Well, we'll see.
6 But do you feel like you're
7 okay, or do we need to reset this for
8 tomorrow?
9 A. No.
10 Q. Want to go forward now?
11 A. We can go forward.
12 Q. Okay. Great.
13 Well, my name is Tricia
14 Herzfeld, and I am one of the attorneys for
15 the plaintiffs in the Tennessee state
16 litigation known as the Staubus and Dunaway
17 cases in state court in Tennessee.
18 MS. HERZFELD: Before I start
19 with my questioning, I just wanted to
20 officially lodge an objection on
21 behalf of my clients that the
22 plaintiffs in the Staubus and the
23 Dunaway matter have not -- they've
24 been cross-noticed in this case but
25 have not been provided documents by

Page 303

1 Mallinckrodt in a timely way, nor in
2 compliance with the order issued out
3 of the MDL.
4 According to that order,
5 Mallinckrodt was required to produce
6 Mr. Rausch's complete and total
7 custodial file by November 2nd, 14
8 days in advance of this noticed
9 deposition. Mallinckrodt continued to
10 produce thousands of Mr. Rausch's
11 custodial documents after
12 November 2nd, finally concluding on
13 November 12, 2018, just a few days
14 before we came here today.
15 As required, 14 days before
16 this deposition Mallinckrodt stated
17 that Mr. Rausch had no
18 Tennessee-specific knowledge. The
19 Staubus and Dunaway plaintiffs aren't
20 sure if that is actually true, if you
21 have no knowledge about Tennessee
22 whatsoever, but we intend to ask you
23 questions about Tennessee, regardless.
24 By failing to abide by the
25 protocol, the plaintiffs in Staubus

Page 304

1 and Dunaway have been prejudiced in
2 their ability to prepare for this
3 deposition.
4 Additionally, the Tennessee
5 Drug Dealer Liability Act claims at
6 issue in the Tennessee litigation have
7 different elements and require
8 different discovery and areas of
9 inquiry than the MDL.
10 Also, the Tennessee Rules of
11 Civil Procedure do not place any time
12 restrictions on the length of
13 depositions. The Staubus and Dunaway
14 plaintiffs have requested two hours to
15 depose Mr. Rausch today, in addition
16 to the MDL's deposition time. We
17 requested it nine days before this
18 scheduled deposition, and we're happy
19 that we could work that out with the
20 parties.
21 But regardless, if for some
22 reason there are additional documents
23 that come forward at a later date, we
24 would be moving to redepose Mr. Rausch
25 at that time based on the violations

Page 305

1 I've just stated.
2 I'm sure you've got something
3 you'd like to say.
4 MR. TSAI: Yeah. For the
5 record, Mallinckrodt's position is
6 quite different from counsel's
7 recitation, and we reserve our rights
8 accordingly.
9 MS. HERZFELD: Great.
10 MR. TSAI: You can go ahead.
11 QUESTIONS BY MS. HERZFELD:
12 Q. Okay. Mr. Rausch, have you
13 ever been to Tennessee?
14 A. No, I have not.
15 Q. Okay. You haven't been for
16 pleasure or for work?
17 A. I drove through Nashville to go
18 to Florida.
19 Q. Okay. Did you stop?
20 A. No.
21 Q. Okay. Do you know when that
22 was?
23 A. No, not offhand.
24 Q. Since you retired?
25 A. Before I retired.

Page 306

1 Q. Okay. Okay. And do you have
2 any friends or family that live in Tennessee?
3 A. No.
4 Q. Okay. And when you left
5 Mallinckrodt, did you have any stock options
6 with Mallinckrodt?
7 A. No.
8 Q. Okay. Have you ever owned any
9 stock in Mallinckrodt?
10 A. Years ago, but they've all been
11 cashed.
12 Q. Okay. And was that part of a
13 compensation package for you?
14 A. It was -- it was part of a
15 management program.
16 Q. Okay.
17 A. The stock options were given at
18 a particular price. They had nothing to do
19 with sales or anything like that.
20 Q. Okay. And what year was that?
21 A. Oh, gosh. This is before
22 probably 2000.
23 Q. Okay. And was it just a
24 one-time thing, or was it kind of year after
25 year?

Page 307

1 A. It was for three or four years,
2 and then they raised the level that they
3 would give stock options, and I was no longer
4 in the program.
5 Q. Okay. When you say "they
6 raised the level" --
7 A. Of participation, as far as it
8 went from managers up to director level, I
9 believe.
10 Q. And you were at what level?
11 A. Manager.
12 Q. And so they took managers out
13 of the availability?
14 A. Correct.
15 Q. Okay. And how much would you
16 say your stock options were worth when you
17 cashed them in?
18 A. I don't remember anymore.
19 Q. Like 10,000? Hundred thousand?
20 A. Some of them weren't worth
21 anything because the stock dropped.
22 Q. Okay.
23 A. No less than -- probably less
24 [REDACTED] but I'm
25 guessing there.

Page 308

1 Q. Okay.
2 A. I didn't go out and buy a new
3 house or anything.
4 Q. So you think roughly less than
5 \$ [REDACTED]
6 A. Correct.
7 Q. Okay. Great.
8 Okay. Would you agree with the
9 statement that the opioid crisis seems to be
10 worse in some areas of the country?
11 MR. TSAI: Object to the form.
12 THE WITNESS: Would I agree to
13 that? I don't have that information.
14 QUESTIONS BY MS. HERZFELD:
15 Q. Okay. You said before that you
16 did know -- have some knowledge about the
17 opioid crisis in this country.
18 A. From the news, yes.
19 Q. Okay. And do you have any
20 information about particular regions where
21 the opioid crisis may be worse?
22 A. No, I haven't really followed
23 it since I've been retired.
24 Q. You haven't followed the opioid
25 crisis news at all since you've been retired?

Page 309

1 A. Well, I've followed it. I've
2 seen it on the news, but it didn't talk
3 specifically about areas that were of greater
4 concern than others.
5 Q. Okay. Have you read any books
6 about the opioid crisis?
7 A. No.
8 Q. Okay. Have you heard
9 particularly that the opioid crisis is
10 particularly bad in Appalachia?
11 A. No, I have not.
12 Q. Okay. What about West
13 Virginia?
14 A. No.
15 Q. What about Kentucky?
16 A. No.
17 Q. Virginia?
18 A. No.
19 Q. How about Tennessee?
20 A. No.
21 Q. You've never heard anything
22 about the opioid crisis in Tennessee?
23 A. Not that I remember.
24 Q. Okay. What about Florida? Do
25 you know anything about there being an opioid

Page 310

1 crisis in Florida?

2 A. Back in the -- when I was still

3 employed, there was some information about

4 Florida. I remember some news about Florida

5 being a place of concern for the DEA, yes.

6 Q. Okay. And do you know where

7 you obtained that information?

8 A. From the news.

9 Q. Okay. Did you ever obtain that

10 information through your employment with

11 Mallinckrodt?

12 MR. TSAI: Objection to this

13 line of questioning. It's not

14 Tennessee-specific.

15 But go ahead.

16 THE WITNESS: Karen Harper, our

17 DEA compliance officer, brought it up

18 to our attention.

19 QUESTIONS BY MS. HERZFELD:

20 Q. Okay. And what information did

21 she give you?

22 A. She just noted that the DEA had

23 sent out a bullet that there was some issues

24 in Florida.

25 Q. Okay. And do you know roughly

Page 311

1 what year that was?

2 A. I'd be guessing. I don't know.

3 Probably -- I'd be guessing.

4 Q. The '80s? '90s?

5 A. Oh, 2000s.

6 Q. 2000s.

7 Okay. Do you think it was

8 before or after 2010?

9 A. Probably before.

10 Q. Okay. And did you make any

11 changes based on -- to your job and your job

12 duties based on that information that you

13 received from Karen Harper about Florida?

14 A. Well, I believe, as you can see

15 from the documents that we were reviewing or

16 from what we talked about, that there was a

17 growing concern from the DEA about diversion,

18 and that's part of the reason why we enhanced

19 our -- our program that we had in place,

20 suspicious order program.

21 Q. Okay. And so you believe that

22 the change in your suspicious order program

23 was because of this information about

24 Florida?

25 MR. TSAI: Object to the form.

Page 312

1 THE WITNESS: Well, no, I

2 didn't say that.

3 QUESTIONS BY MS. HERZFELD:

4 Q. Oh, okay. I want to make sure

5 I understand what you're saying, so correct

6 me.

7 A. Yes. As I said, it was because

8 the DEA was saying that there was increased

9 diversion, and they were asking us to enhance

10 our programs.

11 Q. Okay. So when the DEA was

12 saying there was increased diversion, the way

13 you took that was decreased diversion all

14 over the country, but you knew specifically

15 about issues in Florida?

16 A. Yes, there was bullets put out

17 by the DEA to our DEA compliance people, and

18 they passed on information about that.

19 Q. Okay. So you received specific

20 information about Florida?

21 A. From what I remember, yes.

22 Q. Do you remember any other

23 states?

24 A. I don't.

25 Q. Okay. Were you aware that

Page 313

1 people were traveling from other states to

2 Florida for the purpose of obtaining opioids?

3 A. I was.

4 Q. And how did you become aware of

5 that?

6 MR. TSAI: Objection. Vague as

7 to time.

8 Go ahead.

9 THE WITNESS: Through what I

10 was just talking about, information

11 that Karen passed on to us.

12 QUESTIONS BY MS. HERZFELD:

13 Q. Okay. Did you know that people

14 from Tennessee specifically were going to

15 Florida to get opioids?

16 MR. TSAI: Objection. Vague as

17 to time.

18 THE WITNESS: No, not

19 specifically.

20 QUESTIONS BY MS. HERZFELD:

21 Q. Since 2000, that people were

22 going from Tennessee to Florida to get

23 opioids, were you aware of that?

24 A. Was there a question there?

25 Q. Yes.

Page 314

1 Were you aware of that?

2 A. No.

3 Q. Okay. Did the suspicious order

4 monitoring team monitor Tennessee news

5 articles?

6 A. No.

7 Q. Okay. Did the suspicious order

8 monitoring team monitor social media within

9 Tennessee?

10 A. No.

11 Q. Okay. Did the suspicious order

12 monitoring team review Tennessee disciplinary

13 actions of pharmacists and prescribers?

14 A. Not that I'm aware of.

15 Q. Okay. Did the suspicious order

16 monitoring team review third-party data for

17 red flags of diversion in Tennessee?

18 A. I don't know what the

19 compliance group was monitoring.

20 Q. Okay. And that would have been

21 done through the compliance group?

22 A. Correct.

23 Q. Did you ever review IMS Health

24 data or any other data to determine

25 suspicious orders in Tennessee?

Page 315

1 A. No, I did not.

2 Q. Okay. Would that have been

3 within your purview or that would have been

4 the compliance department?

5 A. That would have been

6 compliance.

7 Q. Okay. Did the suspicious order

8 monitoring team discuss red flags that could

9 indicate diversion in Tennessee with you or,

10 to your knowledge, to your team?

11 A. Say that again.

12 Q. Did the suspicious order

13 monitoring team discuss red flags that could

14 have indicated diversion in Tennessee with

15 you, or was there a discussion amongst the

16 team?

17 A. No.

18 Q. Okay.

19 A. Not that I remember.

20 Q. Okay. Did the suspicious order

21 monitoring team receive reports about

22 possible abuse or diversion of Mallinckrodt

23 opioids by distributors that supplied to

24 Tennessee?

25 MR. TSAI: Objection. Vague as

Page 316

1 to time.

2 THE WITNESS: Not that I

3 remember.

4 QUESTIONS BY MS. HERZFELD:

5 Q. Okay. I'm going to ask you

6 that question from 2000 to 2010.

7 Did you receive any reports

8 about distributors distributing to Tennessee

9 with issues of abuse and diversion?

10 A. I personally did not.

11 Q. Okay. And what about from 2010

12 until the time that you retired?

13 A. I personally did not.

14 Q. Okay. Did you ever hear of

15 either of those things?

16 A. No.

17 Q. Okay. Do you know if anybody

18 in your team would have knowledge if it

19 wasn't you?

20 A. I can't speak for them.

21 Q. Okay. Whose responsibility

22 would it to -- to have that information,

23 reports about suspected abuse and diversion

24 of distributors --

25 A. I believe if there was such

Page 317

1 reports, it would be going to our Karen

2 Harper in compliance.

3 Q. Okay. And would you have been

4 copied on those, or is that information you

5 should have had?

6 A. Would I have been copied? No,

7 not that I can remember.

8 Was it -- how it would affect

9 my job, I don't think so.

10 Q. Okay. What would have been

11 your role?

12 A. My role?

13 Q. Yes, sir.

14 A. In the suspicious order

15 monitoring program?

16 Q. If you had information that a

17 supplier that supplied to Tennessee was

18 having issues with abuse and diversion, you

19 would have a role in that, would you not?

20 A. Well, only an aspect if they

21 were -- they were placing orders with us that

22 would hit our suspicious order monitoring

23 program, that would have been my role.

24 Q. Okay. So I guess that's my

25 question.

Page 318

1 A. Okay.
2 Q. So I'm going to back it up
3 because maybe you didn't understand it.
4 A. Okay.
5 Q. So to your knowledge, you never
6 had any orders that came through that were
7 dinged as suspicious orders through your
8 suspicious order monitoring team from
9 Tennessee or from suppliers that supplied
10 pharmacies in Tennessee?
11 A. No.
12 Q. Okay. Who would know that?
13 A. To my knowledge, we did not
14 have any suspicious orders.
15 Q. Okay. So you would be the
16 person who would know that?
17 A. For that period of time, from
18 2009 to 2010.
19 Q. Okay. Okay. And after that,
20 it would have been?
21 A. I don't remember her name
22 anymore. I had the first name. It was in my
23 notes. I don't -- I'm getting a little -- I
24 don't remember her name. She was in the --
25 the rebate group.

Page 319

1 Q. Okay. So after you left that
2 position, she'd be the one who would know
3 that?
4 A. Right.
5 MR. TSAI: Objection.
6 Duplicative.
7 MS. HERZFELD: Can't be
8 duplicative if he doesn't know the
9 name.
10 MR. TSAI: No, this question
11 was asked before.
12 QUESTIONS BY MS. HERZFELD:
13 Q. Okay. On -- do you know if
14 Mallinckrodt's customer service department
15 had a relationship with any pharmacies in
16 Tennessee?
17 A. I do not know that.
18 Q. Okay. Do you know if any
19 Mallinckrodt employees ever detailed any
20 Tennessee pharmacies?
21 A. Detailed?
22 Q. Went and met with them, like a
23 sales call.
24 A. I don't -- I don't have
25 knowledge of that.

Page 320

1 Q. Okay. What about any detailing
2 of any Tennessee physicians by anyone at
3 Mallinckrodt, do you have any knowledge of
4 that?
5 A. No, I do not.
6 Q. Okay. Were you ever present
7 when opioid abuse or diversion issues in
8 Tennessee were discussed by any other
9 Mallinckrodt employee?
10 A. No.
11 Q. Have you ever seen any memos or
12 paperwork or any sort of a record talking
13 about --
14 A. Not that I can remember.
15 Q. -- abuse and diversion in
16 Tennessee?
17 A. No.
18 Q. Okay. Do you know if anyone on
19 the suspicious order monitoring team, while
20 you were involved with it, ever discussed any
21 problems with abuse or diversion with law
22 enforcement or other officials in Tennessee?
23 A. No, I do not remember that.
24 Q. Okay. Do you know which
25 distributors at Mallinckrodt did business

Page 321

1 with that shipped Mallinckrodt opioids to
2 Tennessee?
3 A. Which distributors we shipped
4 to in Tennessee?
5 Q. Yes, sir.
6 A. I don't recall that, who they
7 were.
8 Q. Okay. What types of records
9 would show who those were, the distributors
10 that shipped to Tennessee?
11 A. Order processing records.
12 Q. Okay. Anything else?
13 A. That would probably -- from my
14 point of view where I came from, order
15 processing would be one of the places that
16 records would be kept.
17 Q. Okay. Can you think of any
18 other spots, or is that the only one you can
19 think of?
20 A. That's the only one I can think
21 of.
22 Q. Okay. Did the suspicious order
23 monitoring team ever break down how many
24 particular pills were being shipped to a
25 state, on a kind of state-by-state basis?

Page 322

1 Did you ever look at that in the aggregate?
2 A. By state by state?
3 Q. Yes, sir.
4 A. Not that I'm aware of.
5 Q. Okay. Or by ZIP code or by
6 city?
7 A. No.
8 Q. Okay. Do you know what
9 percentage of Mallinckrodt opioids were sent
10 to Tennessee?
11 A. I do not.
12 Q. Okay. Do you know if there was
13 ever a consideration in the suspicious order
14 monitoring team about the number of opioids
15 shipped to a particular area compared to that
16 area's population?
17 A. No.
18 Q. Okay. So other than we talked
19 about Florida a little bit just a few minutes
20 ago, you said that the changes were
21 generally -- I'm paraphrasing you, so tell me
22 if I'm saying it incorrectly -- that the DEA
23 generally had some concerns about diversion
24 generally, and you knew specifically about
25 this issue in Florida.

Page 323

1 A. Correct.
2 Q. Based on that information, did
3 you treat Florida any differently than any
4 other state in performing your job
5 responsibilities?
6 A. Not my job responsibilities.
7 Our -- our reports from -- would --
8 nationally for all that would -- would take a
9 look at orders that were being processed from
10 Florida, like any other order, and kick out
11 peculiar orders from them.
12 Q. Okay. So I want --
13 A. At that time, yeah.
14 Q. I want to make sure I
15 understand your answer correctly.
16 So Florida would have been
17 looked at the same as any other state at that
18 point?
19 A. From what I remember.
20 Q. Okay.
21 A. There may have been -- you
22 know, we had a compliance group led by Karen
23 Harper that would visit distributors and
24 that. That may have been one of the areas
25 that they keyed in on. I'm not sure, but

Page 324

1 that would be a possibility.
2 Q. Okay. But to your knowledge,
3 from your perspective, everything was the
4 same?
5 A. From my perspective, correct.
6 Q. Okay. And so that would go for
7 Tennessee as well. Tennessee was never
8 treated differently than any other state?
9 A. Correct.
10 Q. Okay. Did you ever have any
11 discussion with any distributors about
12 problem prescribers in Tennessee?
13 A. No.
14 Q. Did you ever hear a discussion
15 of problem prescribers in Tennessee?
16 A. No.
17 Q. Okay. And what about problem
18 pharmacies?
19 A. No.
20 Q. Okay. Do you know if any
21 distributor orders going to Tennessee ever
22 appeared to be in your peculiar order report
23 or suspicious order report?
24 A. I don't remember. I don't
25 remember.

Page 325

1 Q. Is it possible to determine in
2 the aggregate, year by year, how many of
3 those suspicious orders or peculiar order
4 reports were generated for Tennessee? From
5 Tennessee?
6 A. Is it possible to do that? I
7 guess it's possible. I don't know how it
8 would be done, but I can't answer it any
9 further than that.
10 Q. When you put the information
11 into the computer or database or whatever --
12 A. Right. And looking at how far
13 back you're talking about, whether the data
14 is still available, someone from -- from IS
15 or whatever would have to put together a
16 report, if they could, of the history of
17 orders that were placed by companies in
18 Tennessee.
19 Q. Okay. And do you know what the
20 name of that database was or if there was --
21 A. JD Edwards.
22 Q. JD Edwards?
23 A. That was the order processing
24 system.
25 Q. Okay. And that's what was used

Page 326

1 at the time?

2 A. Yes.

3 Q. Okay. And do you have a

4 designation for state or region or something

5 geographically?

6 A. Yes.

7 Q. Okay. Great.

8 Do you know if there were any

9 Tennessee pharmacies on Mallinckrodt's

10 chargeback restriction list?

11 A. I'm not familiar with the

12 chargeback system.

13 Q. Okay. Do you know if anyone

14 from your team ever communicated with any

15 Tennessee pharmacies?

16 A. No.

17 Q. Did you ever communicate with

18 any Tennessee pharmacies?

19 A. Not that I -- no.

20 Q. Okay. And I'm not -- I may

21 have asked you this question, so if I did, I

22 apologize.

23 You don't recall any suspicious

24 orders coming from Tennessee for diversion or

25 overordering or anything?

Page 327

1 A. No.

2 Q. Okay. Do you have any

3 familiarity with Sunrise Wholesale?

4 A. I've heard of them.

5 Q. In Delray Beach, Florida?

6 A. Yes.

7 Q. Okay. Did you have any

8 involvement with Sunrise Wholesale while you

9 were at Mallinckrodt?

10 A. As far as what?

11 Q. Any discussions about them?

12 Meetings?

13 A. I remember Sunrise being

14 discussed. What was discussed, I don't

15 remember.

16 Q. Okay. Do you recall Tennessee

17 being mentioned in relation to Sunrise?

18 A. No.

19 Q. Okay. Do you know if Sunrise

20 Wholesale had been flagged for suspicious

21 orders or peculiar orders?

22 A. I don't remember.

23 Q. Okay. Did you ever learn at

24 some point that Sunrise Wholesale was being

25 investigated by the DEA?

Page 328

1 A. I don't remember.

2 Q. Okay. Did you ever attend any

3 meetings about the DEA investigation of

4 Sunrise Wholesale?

5 A. No, I didn't.

6 Q. Okay. Did you hear about a

7 sting operation in 2009 of -- in Tennessee

8 relating to Sunrise Wholesale in Florida?

9 A. No, I didn't.

10 Q. Okay. Have you ever spoken or

11 do you know a person named Pete Kleissle?

12 A. Doesn't ring a bell.

13 Q. Okay. DEA agent?

14 A. No, doesn't -- sorry.

15 Q. That's okay.

16 Have you ever spoken to a DEA

17 agent, to your knowledge?

18 A. Not that I can remember.

19 Q. Okay.

20 A. It was -- most of our

21 communication with the DEA was through Karen

22 Harper's group.

23 Q. Okay.

24 A. Our compliance group, I should

25 say.

Page 329

1 Q. Okay. Have you ever heard of

2 Dr. Barry Schultz?

3 A. Does not ring a bell.

4 Q. Okay. And do you know who

5 would have been involved in a decision to

6 continue to ship to Sunrise Wholesale after

7 July of 2009?

8 A. Who would have been involved?

9 Q. Who would have made that

10 decision.

11 Would that have been you?

12 A. Whether we were going to -- no,

13 that was above my pay grade.

14 Q. Okay.

15 A. It would have been our DEA

16 compliance group. They would have informed

17 us that we were no longer going to ship to

18 them.

19 Q. Okay. And if they didn't, you

20 would just continue shipping to them if

21 they're an existing customer?

22 MR. TSAI: Object to the form.

23 THE WITNESS: That's -- that's

24 asking me to -- I don't -- I'll answer

25 that by saying I don't think we do,

Page 330

1 because the compliance group would
2 have informed us not to ship to them
3 anymore.
4 QUESTIONS BY MS. HERZFELD:
5 Q. If there was already a raid?
6 A. Yes.
7 Q. Okay. But you don't have any
8 knowledge specifically about --
9 A. No, I don't.
10 Q. -- Sunrise?
11 Okay. Do you know who Steve
12 Becker is?
13 A. I do.
14 Q. Who is Steve Becker?
15 A. Steve Becker was a salesman.
16 Q. Okay. A salesman at
17 Mallinckrodt?
18 A. Correct.
19 Q. Okay. Do you recall attending
20 a meeting with Steve Becker in July of 2010
21 to talk about the oxy situation?
22 A. I don't recall it.
23 Q. Have you ever been in a meeting
24 with Steve Becker that you've talked about
25 diversion or oxy or anything like that?

Page 331

1 A. I don't remember.
2 Q. Okay. Do you recall ever
3 discussing Tennessee with Steve Becker?
4 A. No.
5 Q. Okay. Do you know a
6 distributor named KeySource Medical, Inc.?
7 A. I remember the name.
8 Q. Okay. Do you remember anything
9 specific about them?
10 A. They were a customer at some
11 point.
12 Q. Okay. In Florida maybe?
13 A. I would be guessing that they
14 were in Florida.
15 Q. Okay. Do you know if you had
16 any interaction with KeySource Medical?
17 A. No.
18 Q. Okay. Do you know if that --
19 you ever heard anybody mention or read in any
20 documents any interactions between KeySource
21 Medical and Tennessee?
22 A. No.
23 Q. Okay. Have you ever been to
24 Cincinnati?
25 A. I have been to Cincinnati.

Page 332

1 Q. Did you ever go to Cincinnati
2 for a meeting to discuss suspicious order
3 monitoring?
4 A. I believe we did.
5 Q. Okay. When do you think that
6 was?
7 A. I don't remember. Probably
8 2009.
9 Q. Okay. And do you recall what
10 the purpose of the meeting was?
11 A. To discuss their suspicious
12 order program, look to observe their
13 facility.
14 Q. When you say "them," who do you
15 mean?
16 A. Oh, I'm sorry.
17 Q. That's okay.
18 A. I believe -- I believe Karen --
19 well, I think Karen Harper was involved, but
20 I don't remember for sure. I believe our
21 VP -- VP of sales was involved. She went
22 along. And also our director of marketing
23 was also involved.
24 But our purpose, I believe, at
25 the time was to see what monitoring they had

Page 333

1 in their system for suspicious orders, that
2 type of thing.
3 Q. And when you say "monitoring in
4 their system" --
5 A. What their suspicious order
6 program was, if they had one, and what
7 their -- because we were doing some due
8 diligence, as I mentioned earlier, that we
9 were trying to outreach to other companies
10 that we dealt with to see if we could help
11 them in developing suspicious order reporting
12 if they didn't have it already.
13 Q. And which company were you
14 visiting?
15 A. I don't remember the name.
16 Q. Okay. You just knew it was in
17 Cincinnati and there was a big group of
18 people?
19 A. Yes.
20 Q. Okay. Okay. And you didn't
21 attend a DEA meeting in 2011 in Arlington,
22 Virginia?
23 A. No.
24 Q. Okay. I'm assuming that
25 because you said you've never met a DEA

Page 334

1 agent.
2 A. Right.
3 Q. Okay. Do you know anything
4 about Masters Pharmaceutical?
5 A. I remember the name, yes.
6 Q. Okay. And did you interact at
7 all with Masters Pharmaceutical?
8 A. Were they in Cincinnati?
9 Q. I wish I could answer that
10 question for you. I can't.
11 A. I don't -- okay. Because I
12 couldn't remember what the name of the
13 company was in Cincinnati.
14 Q. I don't have that information.
15 A. Did I interact personally with
16 them?
17 Q. Yes.
18 A. No.
19 Q. Do you know if anyone from your
20 team did?
21 A. By "your team," do you mean
22 compliance people?
23 Q. Yes, sir.
24 A. I'm sure there was some
25 inter -- I believe so.

Page 335

1 Q. Okay. Do you recall them
2 having any particular issues with suspicious
3 or peculiar orders?
4 A. I don't remember.
5 Q. Okay. Do you remember anybody
6 particularly kind of being repeat customers
7 for issues for suspicious or peculiar orders?
8 A. We didn't have -- in the time
9 frame that I had, we didn't have any
10 suspicious orders.
11 Q. Okay. So you've -- as was
12 already discussed, you would track those down
13 and eventually the order would go through?
14 A. Right.
15 Q. Okay. What about the Harbor
16 Medical Group in Livonia, Michigan, do you
17 recall any interactions with them?
18 A. I remember the name.
19 Q. Okay. And do you remember
20 anything particularly about them?
21 A. As far as --
22 Q. Suspicious orders?
23 A. -- compliance, that type of
24 thing?
25 Q. Yes, sir.

Page 336

1 A. I remember discussions about
2 Harbor being reviewed -- reviewed by the DEA.
3 Q. Okay. Do you remember who was
4 having those discussions?
5 A. The DEA.
6 Q. Okay. And do you recall who
7 told you?
8 A. I believe that was probably
9 from Karen Harper.
10 Q. Okay. And did Ms. Harper or
11 anyone else ever mention Tennessee in
12 connection with the Harbor Medical Group?
13 A. Not that I remember.
14 MS. HERZFELD: Okay. I don't
15 think I have any further questions for
16 this witness at this time. Thank you.
17 VIDEOGRAPHER: We're going off
18 the record at 5:46 p.m.
19 (Off the record at 5:46 p.m.)
20 VIDEOGRAPHER: We are back on
21 the record at 5:47 p.m.
22 CROSS-EXAMINATION
23 QUESTIONS BY MR. TSAI:
24 Q. Mr. Rausch, do you recall your
25 testimony earlier today regarding Mr. Howard

Page 337

1 Davis?
2 A. I do.
3 Q. Have you ever met Howard Davis?
4 A. Not that I can recall.
5 Q. Have you ever spoken with
6 Howard Davis?
7 A. Not that I can recall.
8 Q. Do you know whether Howard
9 Davis had any experience as of November 2010
10 in regard to developing or implementing any
11 suspicious order monitoring program?
12 A. I do not know if he did or not.
13 Q. Could you pull up Exhibit 10?
14 A. (Witness complies.)
15 Q. And if I could refer you to
16 Section 5, entitled "Background
17 Documentation."
18 A. Okay.
19 Q. Is it your understanding that
20 this is Mr. Davis' personal recommendation as
21 to additional background documentation for
22 Mallinckrodt to request for its customers?
23 A. That's my understanding.
24 Q. Are Mallinckrodt's customers
25 individual pharmacies?

Page 338

1 A. No.
 2 Q. Are Mallinckrodt's customers
 3 patients or end users?
 4 A. No.
 5 Q. Are Mallinckrodt's customers
 6 physicians or other prescribers?
 7 A. No.
 8 Q. Are Mallinckrodt's customers
 9 distributors or other manufacturers?
 10 A. Yes.
 11 Q. If you could go back to
 12 Section 5, and do you see the bullet point --
 13 one of the background documentation items
 14 recommended by Mr. Davis as of November 2010
 15 in this memo is "Do they self-medicate?"
 16 Do you see that?
 17 A. Yes.
 18 Q. Could Mallinckrodt ask a
 19 distributor whether it self-medicates?
 20 MR. KAWAMOTO: Objection to
 21 form.
 22 THE WITNESS: No.
 23 QUESTIONS BY MR. TSAI:
 24 Q. If you could go to the very
 25 next bullet point: "Are they treating family

Page 339

1 members?"
 2 Do you see that?
 3 A. Yes.
 4 Q. Could Mallinckrodt ask one of
 5 its distributor customers whether it is
 6 treating family members?
 7 A. No.
 8 Q. Could Mallinckrodt, looking at
 9 the next bullet point, ask one of its
 10 distributor customers how many patients do
 11 they see daily?
 12 A. No.
 13 Q. Going to the next bullet point,
 14 recommended by Mr. Davis, could Mallinckrodt
 15 ask one of its distributor customers about
 16 the number of patients to whom they dispense
 17 controlled substances?
 18 A. No.
 19 Q. Do these recommendations even
 20 make sense for a manufacturer like
 21 Mallinckrodt?
 22 A. Not to me.
 23 Q. And do you agree with
 24 Mr. Davis' recommendations here?
 25 A. No.

Page 340

1 MR. TSAI: No further
 2 questions.
 3 MR. KAWAMOTO: Okay. I believe
 4 I'm permitted to recross.
 5 MR. TSAI: Yes. It's a
 6 minute-for-minute for recross.
 7 MR. KAWAMOTO: I guess I have
 8 seven minutes or six minutes.
 9 REDIRECT EXAMINATION
 10 QUESTIONS BY MR. KAWAMOTO:
 11 Q. Okay. So, Mr. Rausch, your
 12 counsel asked you a number of questions
 13 regarding Section 5 relating to the types of
 14 information that could be solicited; is that
 15 fair?
 16 A. That's correct.
 17 Q. Could this information have
 18 been solicited from a distributor's
 19 customers?
 20 A. From a distributor's customer?
 21 Q. Yes.
 22 A. I guess it could be.
 23 Q. So this is information that
 24 could be gathered on Mallinckrodt -- on the
 25 customers of Mallinckrodt's customer,

Page 341

1 correct?
 2 A. Yes.
 3 Q. And using the chargeback data,
 4 Mallinckrodt could -- Mallinckrodt had an
 5 understanding of who the distributor's
 6 customers were; is that correct?
 7 MR. TSAI: Object to the form.
 8 THE WITNESS: I don't know how
 9 the chargeback data worked. I was not
 10 familiar with that process.
 11 QUESTIONS BY MR. KAWAMOTO:
 12 Q. Is it your understanding that
 13 the chargeback data could be used to identify
 14 the end users?
 15 A. I believe so.
 16 Q. Okay.
 17 A. But to -- do they
 18 self-medicate? I don't think they could find
 19 that information out and some of the other
 20 questions here.
 21 MR. KAWAMOTO: Okay. No
 22 further questions.
 23 THE WITNESS: Okay.
 24 VIDEOGRAPHER: We're going off
 25 the record at 5:51 p.m.

<p style="text-align: right;">Page 342</p> <p>1 (Deposition concluded at 5:51 p.m.) 2 ----- 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>	<p style="text-align: right;">Page 344</p> <p>1 INSTRUCTIONS TO WITNESS 2 3 Please read your deposition over 4 carefully and make any necessary corrections. 5 You should state the reason in the 6 appropriate space on the errata sheet for any 7 corrections that are made. 8 After doing so, please sign the 9 errata sheet and date it. You are signing 10 same subject to the changes you have noted on 11 the errata sheet, which will be attached to 12 your deposition. 13 It is imperative that you return 14 the original errata sheet to the deposing 15 attorney within thirty (30) days of receipt 16 of the deposition transcript by you. If you 17 fail to do so, the deposition transcript may 18 be deemed to be accurate and may be used in 19 court. 20 21 22 23 24 25</p>
<p style="text-align: right;">Page 343</p> <p>1 CERTIFICATE 2 3 I, CARRIE A. CAMPBELL, Registered 4 Diplomate Reporter, Certified Realtime 5 Reporter and Certified Shorthand Reporter, do 6 hereby certify that prior to the commencement 7 of the examination, James Rausch was duly 8 sworn by me to testify to the truth, the 9 whole truth and nothing but the truth. 10 I DO FURTHER CERTIFY that the 11 foregoing is a verbatim transcript of the 12 testimony as taken stenographically by and 13 before me at the time, place and on the date 14 hereinbefore set forth, to the best of my 15 ability. 16 17 I DO FURTHER CERTIFY that I am 18 neither a relative nor employee nor attorney 19 nor counsel of any of the parties to this 20 action, and that I am neither a relative nor 21 employee of such attorney or counsel, and 22 that I am not financially interested in the 23 action. 24 25 CARRIE A. CAMPBELL, NCRA Registered Diplomate Reporter Certified Realtime Reporter Notary Public</p> <p>Dated: November 23, 2018</p>	<p style="text-align: right;">Page 345</p> <p>1 ACKNOWLEDGMENT OF DEPONENT 2 3 4 I, _____, do 5 hereby certify that I have read the foregoing 6 pages and that the same is a correct 7 transcription of the answers given by me to 8 the questions therein propounded, except for 9 the corrections or changes in form or 10 substance, if any, noted in the attached 11 Errata Sheet. 12 13 _____ 14 James Rausch DATE 15 16 Subscribed and sworn to before me this 17 _____ day of _____, 20 _____. 18 My commission expires: _____ 19 Notary Public 20 21 22 23 24 25</p>

Page 346

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Page 347

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